

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE**

COOS COUNTY,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC F/K/A ACTAVIS PLC;
ACTAVIS, INC. F/K/A WATSON
PHARMACEUTICALS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC;
ACTAVIS PHARMA, INC. F/K/A WATSON
PHARMA, INC.; ENDO HEALTH
SOLUTIONS INC.; MALLINCKRODT LLC;
MCKESSON CORPORATION; CARDINAL
HEALTH, INC.; AMERISOURCEBERGEN
CORPORATION; CVS HEALTH
CORPORATION; RITE-AID OF
MARYLAND, INC.; WALGREENS BOOTS
ALLIANCE, INC.; WALMART, INC; DR.
MARK WEINREB; DR. MICHAEL DIPRE;
CHRISTOPHER CLOUGH; DR. ERIK
KNIGHT; RICHARD SACKLER; JONATHAN
SACKLER; MORTIMER D.A. SACKLER;
DAVID SACKLER; KATHE SACKLER;
ILENE SACKLER LEFCOURT; BEVERLY
SACKLER; THERESA SACKLER; CECIL
PICKETT; PAULO COSTA; RALPH
SNYDERMAN; FRANK BOER; JUDY
LEWENT; JOHN STEWART; CRAIG
LANDAU; MARK TIMNEY; RUSSELL
GASDIA; TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER
FAMILY; THE P.F. LABORATORIES, INC.
AND DOE DEFENDANTS,

CIVIL ACTION NO.:

COMPLAINT

JURY TRIAL DEMANDED

Defendants.

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Plaintiff, Coos County (“Plaintiff” or “County”), by and through counsel, advances this civil action against Defendants Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; and Mallinckrodt, LLC (collectively, “Manufacturers” or “Manufacturer Defendants”); Defendants McKesson Corporation, Cardinal Health Inc., and Amerisource Drug Corporation (collectively, “Distributors” or “Distributor Defendants”); and Defendants CVS Health Corporation, Rite-Aid of Maryland, Inc., Walgreens Boots Alliance, Inc., and Walmart, Inc. (“Retail Pharmacies” or “Defendant Retail Pharmacies”) (the Manufacturers, Distributors and Retail Pharmacies collectively referred to as “Defendant Pharmaceutical Companies”); and Defendants Dr. Mark Weinreb, Dr. Michael DiPre, Dr. Erik Knight and Christopher Clough (the “Individual Defendants”); and Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, David Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, Cecil Pickett, Paulo Costa, Ralph Snyderman, Frank Boer, Judy Lewent, John Stewart, Craig Landau, Mark Timney, Russell Gasdia, for the Benefit of Members of the Raymond Sackler Family, The P.F. Laboratories, Inc (collectively, “Additional Purdue Defendants”) and Doe Defendants (all the foregoing parties collectively referred to as “Defendants”) as follows:

INTRODUCTION

1. Ostensibly authorized to sell their highly addictive drugs, Defendants' marketing practices and other conduct throughout the time period at issue in this civil action were unlawful and reprehensible.

2. Defendants knowingly and willfully created epidemic levels of addiction by flooding the market with a supply of opioids that greatly exceeded any legitimate pharmaceutical need. They did this solely to increase sales and line their pockets with obscene profits.

3. Throughout the time period referenced in this complaint, Defendants possessed no concern for the human and economic carnage they left in their wake. The ultimate goal and focus of Defendants' fraudulent and unlawful marketing, distribution and sales programs was profit.

4. The opioid crisis is a public nuisance that is a significant and ascertainable drain on the County's finances. Defendants put profits above the health, well-being and public good of Coos County, its families, residents, consumers, and taxpayers. The multi-faceted costs of this public nuisance arise from unbridled corporate power and greed.

5. As a result of Defendants' misconduct and unlawful acts, the County (and other municipalities across the United States) will, for decades, be strapped with related costs. Those related costs are the ascertainable damages claimed herein.

6. Plaintiff Coos County spends millions of dollars each year to provide and pay for health care services, veterans services, pharmaceutical care and other necessary services and programs. In response to the opioid crisis the County has been forced unnecessarily expend exorbitant amounts of money.

7. Coos County also provides a wide range of other services to its residents, including law enforcement, firefighting and emergency and/or first responder services, public health and

safety services for families and children, mental health and substance abuse treatment, counseling, education, rehabilitation services, and public assistance.

8. The County is also responsible for partially funding a medical insurance plan for its employees.

9. At all times relevant to this complaint, Defendants knew, and had known for years, that opioids are highly addictive and subject to abuse.

10. At all times relevant to the complaint, Defendants had actual knowledge that their drugs were highly addictive if used long term (pain lasting three months or longer, hereinafter referred to as “chronic pain”) or for chronic non-cancer pain. Also, they had actual knowledge that some percentage of the markets they unlawfully targeted would become addicted in as little as seven days; yet they fraudulently – and inhumanely - concealed the truly addictive qualities and nature of the drugs they peddled.

11. Through lies and unsupported medical or scientific conclusions, Defendants created an alternative reality in which their drugs posed no risk and were the best and proper treatment for a multitude of conditions and symptoms, and where providers of medical care who did not prescribe Defendants’ drugs were, in essence, abusing their patients.

12. This civil action seeks to recoup monies expended by the County in response to and as a result of the opioid epidemic directly and proximately caused by Defendants’ misconduct referenced herein.

13. This action also seeks to have Defendants rightfully pay for the costs of the future efforts that are required to mitigate damages directly and proximately arising from their misconduct. Future damages will address the economic costs of the societal destruction caused by Defendants’ willful and knowing actions.

14. Addiction is an extremely consequential risk which may condemn addicted patients to dependence, compulsive use, a lifetime of battling relapse, or a dramatically heightened risk of serious injury or death. Not a single Defendant disputes this fact.

15. From the outset, Manufacturer Defendants knew that extraordinary Marketing Efforts (as defined below) would be required to change accepted medical norms. This was at least in part because prior to these unlawful unfair and deceptive efforts, some rank and file doctors across the country generally believed that the benefits of opioid use for long-term non-palliative care may not be sufficient to justify the risks associated with its use and not prescribing pain killers was not considered patient abuse.

16. To overcome this marketing obstacle, through methodically implemented unlawful Marketing Efforts Manufacturer Defendants set out to, and did, reset medical norms.

17. Each Manufacturer Defendant directly, and with or through third parties, claimed that the potential for addiction from its drugs was relatively small or non-existent. They unlawfully did so notwithstanding the fact that they possessed no scientific evidence to support such claims. Even worse, their available research actually contradicted the representations they made while marketing their drugs.

18. In addition to denying or falsely minimizing the risk of addiction and abuse generally, Manufacturer Defendants also willfully, knowingly and falsely claimed that their drugs were safer, less addictive, and less likely to be abused or diverted than other or predecessor drugs.

19. Manufacturer Defendants also callously and fraudulently used false information to convince the medical community, individual doctors and the consuming public into believing in the benefits of opioid use for common pain or chronic pain conditions. They accomplished this

through widely disseminated false claims that the treatments were scientifically and medically based.

20. Manufacturer Defendants' Marketing Efforts included an onslaught of false claims advancing false and unsupported statements of (purported) fact and propositions. For example, they advanced the false claim that the use of opioids to treat conditions previously not considered appropriate for opioid use had been found to be a medically appropriate treatment and that that the treatment through opioids for common pain or non-palliative chronic pain conditions was a sound and scientifically based medical breakthrough.

21. Eventually Manufacturer Defendants spent so much money and made such extensive efforts to advance this unscrupulous agenda that they actually succeeded in having the medical community endorse the concept that failing to prescribe opioids constituted patient abuse.

22. Manufacturer Defendants represented as fact the proposition that opioids were an effective treatment for short-term post-surgical and trauma-related pain and for palliative (end-of-life) care.

23. The truth is that opioids should not be prescribed or used long term for non-palliative care except as a last resort.

24. The U.S. Food and Drug Administration (the "FDA") has expressly found that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.¹

25. Opioids are a class of pharmaceuticals that include prescription painkillers like OxyContin and Percocet and generics like oxycodone and hydrocodone as well as illicit drugs like

¹ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

heroin and fentanyl. They are narcotics. Opioids are at the root of an ongoing public health crisis in America.

26. Opioids are narcotics and are regulated as controlled substances.

27. Prescription opioids work by binding to receptors on the spinal cord and in the brain. Similar to the effects of taking heroin, such binding serves to dampen the perception of pain.

28. Also like heroin, opioids also create a euphoric high. That feeling of euphoria is one of the qualities that has been found to make opioids addictive.

29. At certain doses, opioids can slow the user's breathing and cause respiratory depression, possibly to the point of death.

30. At all times relevant to this complaint, Manufacturer Defendants had actual knowledge that with prolonged use, the effectiveness of opioids wanes and requires increases in doses to maintain their noticeable effects.

31. At all times relevant to this complaint, Manufacturer Defendants had actual knowledge that prolonged use markedly increases the risk of significant side effects and addiction.²

32. At all times relevant to this complaint, Manufacturer Defendants had actual knowledge that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days) and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

² See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994). The authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) ("DSM-V") classifies addiction as a spectrum of "substance use disorders" that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this complaint, "addiction" refers to this range of substance use disorders.

33. To expand the market for opioids and realize blockbuster profits, Manufacturer Defendants acted to create a sea of change in the medical and public perception. Following Manufacturer Defendants' willful and knowing, unfair, deceptive and unlawful marketing and lobbying plan, the use of opioids became commonplace not just for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

34. Manufacturer Defendants implemented a willful, knowing, sophisticated and highly deceptive and marketing campaign ("Marketing Efforts") that began during or about 1998.³ The plan took root and deepened during or about 2006 and continues to the present. The goal of the Marketing Efforts was to make blockbuster profits.

35. The means by which Manufacturer Defendants would achieve that end goal was, in part, to reverse the medical understanding of opioids and their acceptable use.

36. Inspired by and based upon the Sackler family's unethical and unlawful business model and strategies, Manufacturer Defendants' Marketing Efforts, over time, did in fact change norms in the medical community. For example, Defendants convinced medical opinion leaders, individual doctors and the consuming public to believe that the benefits of opioid use for common pain or chronic pain conditions was sufficient to justify the risks associated with its use.

37. As a direct and proximate result of Manufacturer Defendants' unfair and deceptive acts and practices, the prescribing of opioids to treat chronic pain long term became commonplace.

38. To ensure the success of their Marketing Efforts and profit goals, Manufacturer Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful, yet false or misleading, scientific and educational materials and advertising that

³ Marketing Efforts also include the efforts of third-party KOLs and Front Groups, as defined herein.

misrepresented the risks, benefits, and superiority of opioids used long term to treat chronic pain; (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids; (c) recruiting prescribing physicians as paid speakers as a means of both securing those physicians' future "brand loyalty" and extending their reach to the physicians' peers; (d) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("Key Opinion Leaders" or "KOLs,") not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Manufacturer Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

39. The Marketing Efforts developed, supported, directed and carried out by Manufacturer Defendants were not designed to present a fair view of how and when opioids could be safely and effectively used. Manufacturer Defendants' unfair and deceptive Marketing Efforts were willfully designed and intended to deceptively convince doctors and patients that the benefits of using opioids to treat common or chronic pain outweighed the risk.

40. Basically, Defendants falsely marketed opioids as able to be safely used for pain with few limitations.

41. Manufacturer Defendants and the third parties whom they recruited and supported obscenely profited through these unfair or unlawful deceptions.

42. Through funding provided by Manufacturer Defendants and others, including Shills, Key Opinion Leaders and the Front Groups (together “Shills”) had their stature in the medical community elevated dramatically. At the same time and as direct by-product of these efforts, Defendants saw dramatic rises in their revenues.

43. Through their own efforts and those of their Key Opinion Leaders and Front Groups, Manufacturer Defendants pioneered a new, overarching, and highly lucrative market for their highly addictive drugs—the chronic pain market.

44. Prior to the unfair and deceptive Marketing Efforts, doctors and patients had long understood that opioids are addictive and, in most circumstances, unsafe for long-term use.

45. Manufacturer Defendants’ unfair and deceptive Marketing Efforts - including the efforts of their Shills - reversed this paradigm.

46. Defendants’ Marketing Efforts promoted that the compassionate treatment of pain *required* opioids.

47. Ignoring the limitations and cautions in their own drugs’ labels, Manufacturer Defendants (a) overstated the benefits of chronic opioid therapy, promised improvement in patients’ function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured their serious risks and adverse outcomes, including the risks of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms.

48. There was, and is, no reliable scientific evidence to support Manufacturer Defendants’ marketing claims, including, but not limited to, those set forth herein.

49. At all times relevant to the complaint, Manufacturer Defendants possessed scientific evidence establishing internally that the claims they made through their Marketing Efforts were false.

50. In ever increasing increments, Manufacturer Defendants also unfairly and deceptively marketed their drugs for indications and benefits that were outside of the drugs' labels.

51. The Marketing Efforts for indications and benefits that were outside of the drugs' label were not supported by substantial evidence of efficacy or by the data Manufacturer Defendants possessed internally.

52. Some of the KOLs have recanted their pro-opioid marketing messages.

53. Some of the KOLs have acknowledged that Defendants' marketing went too far.

54. Notwithstanding the opinions of respected pain specialists, researchers, and physicians who sounded the alarm on the overprescribing of opioids to treat chronic pain, and contrary the internal data they possessed, at all times relevant to this complaint and through this date, Defendants continue to disseminate misleading, unfair or untrue marketing claims.

55. Manufacturer Defendants' unfair and deceptive Marketing Efforts were wildly successful and resulted in mind numbing profits.

56. In 2010, twenty percent of all doctors' visits resulted in the prescription of an opioid. That is nearly double the rate of 2000.

57. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers. In context, in 2012 health care providers wrote enough opioid prescriptions to medicate every adult in America around the clock for a month.

58. Opioids generated \$8 billion in revenue for the drug companies in 2012.

59. Once a niche drug, opioids became the most prescribed class of drugs in the United States. In fact, prescriptions of opioids exceed that of blood pressure, cholesterol, or anxiety drugs.

60. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world.

61. Americans consume 99% of the global hydrocodone supply.

62. It was not a medical or scientific breakthrough that rationalized the prescribing of opioids for chronic pain or that opened the floodgates of opioid use and abuse. Rather, it was the aggressive, well-funded and strategic implementation of unfair and deceptive Marketing Efforts.

63. Defendants' unlawful Marketing Efforts are the direct cause of the catastrophic drug epidemic that has transformed large segments of our population, including in the County, into the "walking dead."

64. The U.S. Centers for Disease Control and Prevention (the "CDC") has declared that our nation has been swept up in an opioid-induced "public health epidemic."⁴ The opioid-induced "public health epidemic was artificially created through Defendants' unlawful conduct, acts and practices as referenced herein.

65. The CDC has also found that that prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012.

66. The opioid crisis has raised significant concern about prescription painkillers. Between 1999 and 2009, overdoses from such drugs rose about 13% annually, though the increase has since slowed to 3% per year.

⁴ CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), available at <http://www.cdc.gov/washington/testimony/2014/t20140429.htm>.

67. According to the CDC, in 2017 there were 47,600 opioid-linked drug fatalities in the United States -- more than the number of deaths linked to breast cancer.

68. One Defendant's own 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008.

69. For every opioid-related death, more than 30 individuals are treated in emergency rooms.

70. The opioid epidemic is a drug problem beyond what this country has ever seen. Dr. Robert DuPont, former director of the National Institute on Drug Abuse, opines that opioids are more destructive than crack cocaine:

[Opioid abuse] is building more slowly, but it's much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then . . . [F]or pain medicine, a one-day dose can be sold on the black market for \$100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.⁵

71. Coos County and the State of New Hampshire have become flooded with prescription opioid pain killers.

72. In 2015, to help battle the opioid epidemic, the State of New Hampshire implemented a Prescription Drug Monitoring Program ("PDMP") to track the amount of opioids dispensed. The first data received for the months of April, May and June of 2015 revealed that

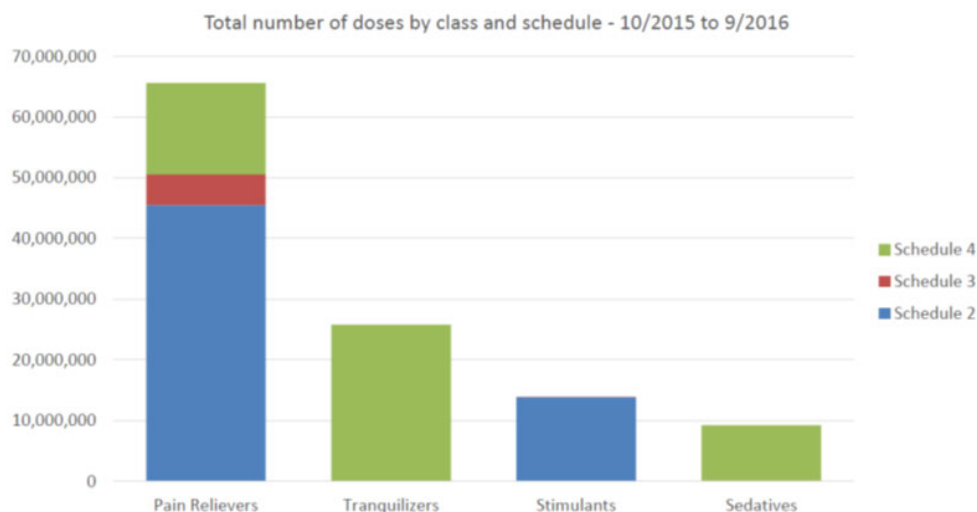
⁵ Transcript, *Use and Abuse of Prescription Painkillers*, The Diane Rehm Show (Apr. 21, 2011), <http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript>.

more than 13 million doses of Schedule II pain killers were dispensed in that short three-month period.⁶

73. According to the 2016 New Hampshire Annual Report, over 50 million schedule II doses were dispensed between October 2014 and September 2015.⁷

74. In context, that equals approximately 50 doses for every man, woman and child in New Hampshire in a one-year period. This far outweighed other types of Schedule II, III, and IV drugs⁸:

Total Number of Doses Across One Year



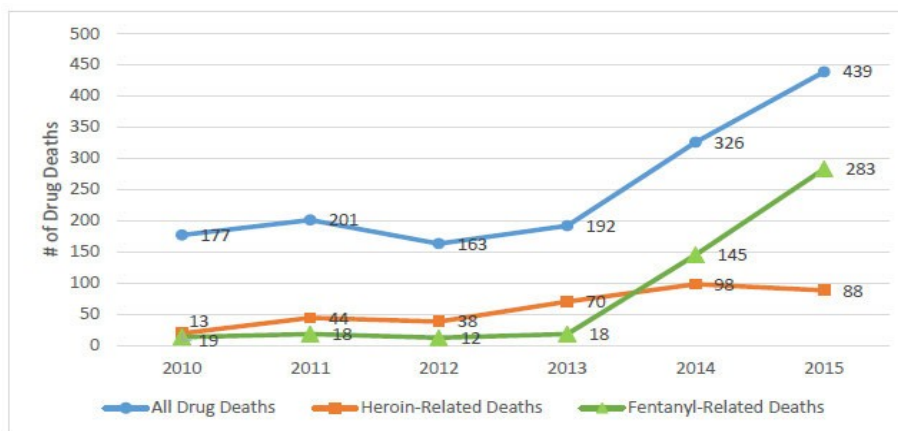
75. It is also worth noting that these 2015 statistics began after there had already been a nationwide decrease in opioid prescribing by physicians. Upon information and belief, these numbers were higher in the years spanning 2010 to 2014.

⁶ New Hampshire Union Leader – “Opioid user numbers in NH are staggering”, *available at* <http://www.unionleader.com/Opioid-user-numbers-in-NH-are-staggering>.

⁷ NH Prescription Drug Monitoring Program Annual Report October 1, 2015 – September 30, 2016.

⁸ *Id.*

76. Data collected for the “New Hampshire HotSpot Report”⁹ regarding the opioid issue in New Hampshire establishes that the numbers have dramatically increased since 2010:¹⁰



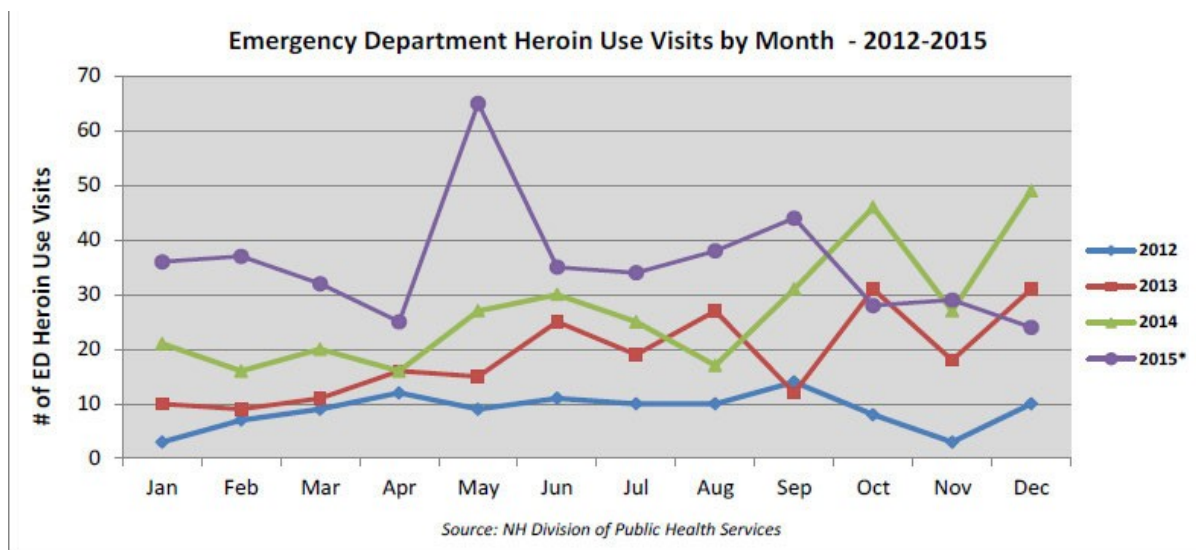
77. Based on this report, there were 1,340 cases of nonfatal and fatal opioid overdoses from January 2015 through October 4, 2016.¹¹ The rate of overdoses has become worse in recent years and there are no signs of it slowing down.

78. The number of emergency department visits as a result of heroin and fentanyl has skyrocketed within New Hampshire, as displayed in the chart below, based on data collected by the “New Hampshire Drug Monitoring Initiative” and included in their January 2016 report:

⁹ The New Hampshire HotSpot Report began in 2016.

¹⁰ “NDEWS New Hampshire HotSpot Report” NDEWS Coordinating Center, October 14, 2016, *available at* <https://ndews.umd.edu/sites/ndews.umd.edu/files/pubs/newhampshirehotspotreportphase1final.pdf>.

¹¹ *Id.* at 5.



79. As a direct result of prescription opioids, Coos County has seen a tremendous increase in heroin-related deaths. According to the New Hampshire Survey on Drug Use and Health, in New Hampshire “heroin use among people ages 12 and older increased 74% between 2009 and 2012.”¹²

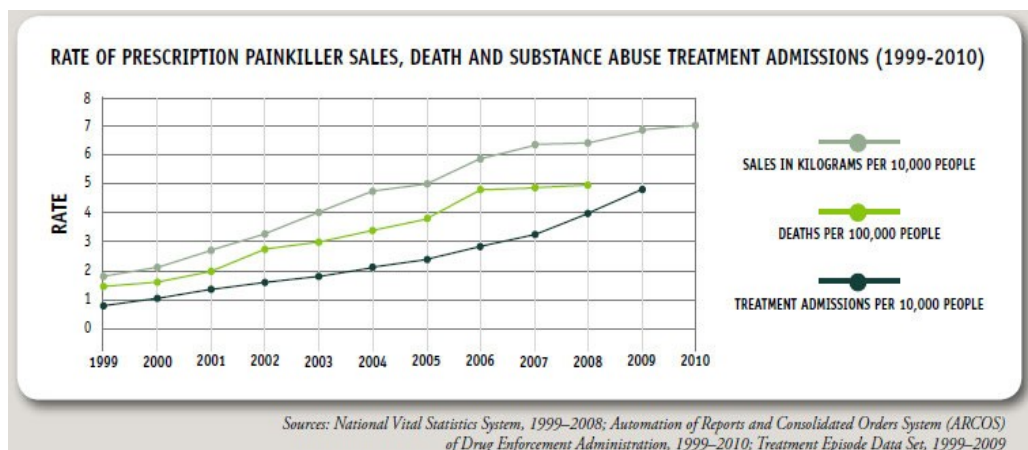
80. Bureau of Drug and Alcohol Services Director Joe Harding stated that this “is related to the prescription drug abuse problem in that people are becoming dependent on prescription opioid pain relievers and switching to heroin because it is cheaper and often more available.”¹³

81. It is widely recognized that a dramatic increase in overdose deaths is directly related to the increase in prescription opioids. According to the CDC New Hampshire 2013 “Prescription Status Report”:: “[t]he sharp rise in opioid overdose deaths closely parallels an equally sharp increase in the prescribing of these drugs. Opioid pain reliever sales in the United States

¹² “DHHS Announces Release of CDC Report on Heroin Deaths,” *available at* <https://www.dhhs.nh.gov/media/pr/2014/10-oct/10022014-heroin.htm>.

¹³ *Id.*

quadrupled from 1999 to 2010. Similarly, the substance abuse treatment admission rate for opioid abuse in 2010 was seven times higher than in 1999.”¹⁴ There was a direct correlation between rates of prescription painkiller sales, death and substance abuse treatment admissions¹⁵:



82. In 2010, drug-related deaths in New Hampshire hit an all-time high of 200, four times as many deaths as in 2000.¹⁶ 80% of these deaths involved prescription medications, primarily opioid pain relievers. In 2013, New Hampshire had 203 deaths caused by drug overdose. In 2014, this number jumped to 334.

83. In 2015, drug-related deaths in New Hampshire further increased to 422, and New Hampshire experienced the second highest rate of drug overdose deaths in the country (34.3 per 100,000), second only to West Virginia. The CDC has said that opioids are the “main driver of drug overdose deaths.”¹⁷

¹⁴ CDC, “Prescription Status Report, 2013, New Hampshire, *available at* <https://www.cdc.gov/psr/2013/prescriptiondrug/2013/nh-pdo.pdf>.

¹⁵ “Collective Action – Collective Impact” – NH’s Strategy for Reducing the Misuse of Alcohol and Other Drugs and Promoting Recovery 2013-2017,” *available at* <https://www.dhhs.nh.gov/dcbcs/bdas/documents/issue-brief-rxdrug.pdf>.

¹⁶ *Id.*

¹⁷ See CDC, “Drug Overdose Death Data,” *available at* <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited May 31, 2018).

84. In 2010, oxycodone became the second most prevalent drug of abuse in New Hampshire state-funded substance abuse treatment, behind only alcohol.¹⁸ Simply put, prescriptions of opioids are the fuel for the opioid epidemic and its devastating effects.

85. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

86. The lesser-known victims of the opioid epidemic are newborn babies. There has been a nationwide epidemic of pregnant women whom are addicted to opioids. The incidences of Neonatal Abstinence Syndrome (“NAS”) skyrocketed in the decade between 2000 and 2011, and have only risen since:¹⁹ The CDC reports that “[a]mong 28 states with publicly available data in HCUP during 1999–2013, the overall NAS incidence increased 300%, from 1.5 per 1,000 hospital births in 1999, to 6.0 per 1,000 hospital births in 2013.”²⁰

Neonatal Abstinence Syndrome NH Infant Discharges by Payer 2000–2011



Data Source: Inpatient Hospital Discharge Data

¹⁸ “Collective Action – Collective Impact” – NH’s Strategy for Reducing the Misuse of Alcohol and Other Drugs and Promoting Recovery 2013-2017,” available at <https://www.dhhs.nh.gov/dcbcs/bdas/documents/issue-brief-rxdrug.pdf>.

¹⁹ CDC, Morbidity and Mortality Weekly Report (MMWR), Incidence of Neonatal Abstinence Syndrome — 28 States, 1999–2013, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm>.

²⁰ New Hampshire Department of Health June 11, 2015, “Neonatal Abstinence Syndrome,” available at <https://www.dhhs.nh.gov/dphs/bchs/mch/documents/nas-data-brief.pdf>.

87. Also, adolescents are abusing opioids in alarming numbers. According to the CDC, more than 12 million Americans age 12 or older used prescription painkillers without a prescription in 2010.²¹

88. On March 7, 2017, New Hampshire held its “Youth Summit on Opioid Awareness.” It was attended by United States Attorney General Jeff Sessions, who stated “[i]n towns all across New Hampshire – from here in Strafford all the way up to the border with Canada – you’ll find families whose lives have been changed forever because of drug and opioid abuse.”²²

89. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor-shopping, use of aliases, and criminal means—to satisfy their cravings.

90. Efforts by doctors to reverse course for a chronic pain patient already on opioids long-term include managing the physical suffering and psychological distress a patient endures while withdrawing from the drugs.

91. The efforts of doctors to reverse course for a chronic pain patient already on opioids long-term is often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply them.

92. Even though they never would have prescribed opioids in the first place absent Manufacturer Defendants’ unfair and deceptive or unlawful Marketing Efforts, some doctors felt

²¹ CDC, *Prescription Painkiller Overdoses in the US* (Nov. 2011), <https://www.cdc.gov/vitalsigns/painkilleroverdoses/> (last visited May 31, 2018).

²² United States Department of Justice Press Release – “Attorney General Jeff Sessions Delivers Remarks at New Hampshire Youth Summit on Opioid Awareness,” *available at* <https://www.justice.gov/opa/speech/attorney-general-jeff-sessions-delivers-remarks-new-hampshire-youth-summit-opioid>.

and continue to feel compelled to continue prescribing opioids to patients who have become dependent on them.

93. The stark rise in heroin-related deaths is a direct and proximate consequence of Defendants' unlawful marketing and over supply of opioid pain medications. As the government became more and more aware of the issues with these drugs and the deceptive marketing, state and federal officials began to crack down on doctors prescribing them.

94. The crack down on doctors resulted in a decrease in the number of prescriptions to those most addicted. As a result, many Americans who had become addicted to opiates were forced to turn to drugs such as heroin. Heroin manufacturers in countries such as Mexico and Colombia saw the increased demand and greatly increased production and trafficking into the United States and communities such as Coos County.

95. According to the National Institute on Drug Abuse, based on data collected from a 2013 study, 80% of heroin users reported using prescription opioids prior to heroin.²³

96. For the reasons referenced herein, opioid abuse has not displaced heroin. Rather the opioid epidemic created by Manufacturer Defendants' unfair and deceptive Marketing Efforts has directly and proximately triggered a resurgence in its use.

97. In turn, this increase in heroin use has resulted in imposing additional burdens on Coos County and the local agencies it supports that address heroin use and addiction.

98. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013.

99. Heroin produces a very similar high to prescription opioids but is often cheaper.

²³ National Institute on Drug Abuse, PRESCRIPTION OPIOIDS AND HEROIN, <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use> (last visited May 22, 2018).

100. While a single opioid pill may cost \$10-\$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price.

101. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to snorting or injecting heroin, but that is the reality of opioid abuse and addiction in Coos County and across the United States.

102. The Coos County residents who suffer from chronic pain deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits.

103. Defendant Manufacturer Defendants' deceptive and unfair Marketing Efforts deprived Coos County residents and their physicians of the ability to make informed medical decisions. Instead, as a direct and proximate result of those Defendants' unfair, deceptive or unlawful Marketing Efforts, important decisions were based on hype, not science.

104. Manufacturer Defendants unlawfully deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and in doing so directly and proximately subjected Coos County to enormous costs and suffering.

105. Indeed, what makes those Defendants' efforts particularly nefarious, heinous, and dangerous is that unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances.

106. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs. Many were not helped by and many were profoundly damaged by Defendants' opioids.

107. Manufacturer Defendants' actions are not permitted or excused by the fact that their labels²⁴ may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain.

108. The FDA's approval did not give Manufacturer Defendants license to misrepresent the risks and benefits, or to falsely claim superiority of opioids for the treatment of conditions for which they are not appropriate.

109. Nor is Manufacturer Defendants' causal role broken by the involvement of doctors. Manufacturer Defendants' Marketing Efforts were ubiquitous, highly persuasive and effective.

110. Manufacturer Defendants' unfair, deceptive or unlawful Marketing Efforts tainted virtually every source doctors could rely on for information and prevented doctors from making informed treatment decisions.

111. Manufacturer Defendants not only targeted pain specialists, but also primary care physicians ("PCPs"), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements.

112. Through their deceptive and unlawful Marketing Efforts, Manufacturer Defendants were also able to falsely change the narrative and in doing so they manipulated well intentioned doctors into believing that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

113. In addition, Defendant Pharmaceutical Companies unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

²⁴ This is excepting Cephalon's labels for Fentora and Actiq.

114. It is estimated that, in 2012, 2.1 million people in the United States suffered from substances use disorders related to prescription opioid pain relievers.²⁵ In 2014, approximately two million Americans were either abusing opioid medications or were dependent on opioids.²⁶ According to the CDC, as of 2016 opioids created a “public health epidemic.”²⁷

115. Defendants’ willful and knowing unfair, deceptive or unlawful actions have resulted in the loss of the lives of residents of Coos County, and the County has incurred great related expense. In addition to the loss of lives, those addicted as well as their families placed a great financial burden on Coos County.

116. Coos County has made significant attempts to fight the epidemic of prescription opioid medications, heroin, and other opioids which has taken over its community. This includes increased law enforcement, educational and community programs, drug support programs, drug take back programs, addiction programs, and the provision of Naloxone to its law enforcement, emergency medical providers, and schools, all at the County’s expense.

117. Deaths from prescription opioids have quadrupled since 1999.

118. From 1999 to 2016, more than 630,000 people died from such overdoses; on average 115 Americans die every day from opioid overdoses.²⁸

²⁵ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

²⁶ CDC, *Injury Prevention & Control: Opioid Overdose, Prescription Opioids, Addiction and Overdose*, available at <http://www.cdc.gov/drugoverdose/opioids/prescribed.html> (last visited May 31, 2018).

²⁷ CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, (Apr. 29, 2014), <http://www.cdc.gov/washington/testimony/2014/t20140429.htm> (last visited May 22, 2018).

²⁸ CDC, *Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic*, (Aug. 30, 2017), <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last visited May 23, 2018).

119. The National Institutes of Health (“NIH”) has not only recognized the opioid abuse problem, it has also identified Defendants’ “aggressive marketing” as a major cause: “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by pharmaceutical companies.”²⁹

120. As shown below, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes “are not really independent causative factors but are in fact the direct result of “the aggressive marketing by pharmaceutical companies.”

121. The rising numbers of persons addicted to opioids have led not only to an increase in health care costs to Plaintiff, but also a major increase in issues such as drug abuse and diversion,³⁰ and crime related to obtaining opioid medications.

122. Coos County has been negatively and severely impacted by the unfair, deceptive, or unlawful fraudulent misrepresentations and omissions by Defendants regarding the safe use and known risks of long-term opioid use.

123. Remarkably, Defendant Pharmaceutical Companies were and remain aware of high levels of product diversion.

²⁹ America’s Addiction to Opioids: Heroin and Prescription Drug Abuse, *available at* <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse> (accessed May 31, 2018) (emphasis added).

³⁰ The CDC defines using or obtaining opioids illegally as “diversion.”

124. As a direct and foreseeable consequence of Defendants' wrongful conduct, Coos County has been required to spend millions of dollars in its efforts to address the problems created by Defendants' wrongful actions.

125. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, alternative addictions following opioid addiction. These costs include, but are not limited to, those related to health care, criminal justice, victimization, social issues, and lost productivity.

126. Manufacturer Defendants' misrepresentations and Marketing Efforts relating to the safety and efficacy of long-term opioid use and Defendants' failure to comply with laws intended to prevent diversion and to ensure a closed system of distribution proximately caused injury to Plaintiff and its residents.

JURISDICTION AND VENUE

127. This Court has jurisdiction over this action in accordance with 28 U.S.C. § 1331 because Plaintiff's claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, raise a federal question. This Court has supplemental jurisdiction over Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claims as to form part of the same case or controversy.

128. This Court has personal jurisdiction over Defendants because they regularly conduct business in New Hampshire. Moreover, Defendants purposefully direct or directed their actions toward New Hampshire. As described herein, some or all Defendants consented to be sued in the New Hampshire by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and they have the requisite minimum contacts with New Hampshire necessary to constitutionally permit the Court to exercise jurisdiction.

129. This Court also has personal jurisdiction over all of the Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts.

130. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and 18 U.S.C. § 1965(a) because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District.

PARTIES

A. Plaintiff.

131. Plaintiff is a County within the State of New Hampshire. At all times relevant to the complaint, Plaintiff provided a wide range of services on behalf of, and for its residents. This includes, but is not limited to, services for families and children, public health, public assistance, law enforcement, and emergency care.

B. Third-Party Bankrupt Entities.

132. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware, Purdue Pharma Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company, Inc. (“PF Co.”) is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, “Purdue”).

133. Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids in Coos County, including the following:

- a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist³¹ tablet first approved in 1995 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014,³² OxyContin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”
- b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, MS Contin was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”
- c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the “management of pain in patients where an opioid analgesic is appropriate.”

³¹ An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

³² The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens’ petition by doctors. The changes were intended to clarify the existing obligation to “make an individualized assessment of patient needs.” The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing “Monitor for signs of misuse, abuse, and addiction” to “[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death.” Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., *Labeling Supplement and PMR [Post-Marketing Research] Required* (Sept. 10, 2013), <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf>.

- d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the “relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief.”
- e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Butrans was indicated for the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.”
- f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
- g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

134. OxyContin is Purdue’s largest-selling opioid. Since 2009, Purdue’s annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from 2006 sales

of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

135. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million—at the time one of the largest settlements with a drug company for marketing misconduct.³³ Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

136. Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation with its principal place of business in Chandler, Arizona.

137. Insys develops, markets, and sells prescription drugs, including Subsys, a sublingual spray of fentanyl, in Coos County.

138. Rhodes Technologies (“Rhodes Tech”) is a Delaware general partnership formed on April 12, 2005 with its principal place of business in Coventry, R.I. At relevant times, Rhodes Tech or its predecessor has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations.

139. Rhodes Technologies Inc. (“Rhodes Tech Inc.”) is a Delaware corporation formed January 28, 1999 with its principal place of business in Coventry, R.I. Rhodes Tech Inc. is a general partner of Rhodes Tech. At relevant times, Rhodes Tech Inc. has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the

³³ <https://oig.hhs.gov/publications/docs/press/2007/SemiannualRelfall2007E.pdf>.

manufacture of pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

140. Rhodes Pharmaceuticals L.P. (“Rhodes Pharma”) is a Delaware limited partnership formed November 9, 2007 with its principal place of business in Coventry, R.I. At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin which is manufactured by Purdue Pharmaceuticals L.P. (“PPNC”), a Delaware limited partnership, which is a subsidiary of Defendant PPLP and which owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

141. Rhodes Pharmaceuticals Inc. (“Rhodes Pharma Inc.”) is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin which is manufactured by PPNC.

142. Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma and Rhodes Pharma Inc. together are referred to herein as the “Rhodes Defendants”.

143. Purdue, Insys and Rhodes are not currently named as Defendants due to their Chapter 11 bankruptcy protections, but they are third-party participants in the unlawful activities described in this complaint.

C. Defendants.

1. Manufacturer Defendants.

144. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”), an Israeli corporation.

145. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

146. Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and has done so since Teva Ltd.'s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Coos County, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva USA and Cephalon, Inc. collectively are referred to herein as "Cephalon."

147. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids in New Hampshire and Coos County:

- a. Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."
- b. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

148. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain. The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million in fines, damages, and penalties.

149. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 through 2009 within Coos County.

150. On September 29, 2008, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services.³⁴ The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and gave them a means to report questionable conduct of its sales representatives; disclose payments to doctors on its web site; and regularly certify that the company has an effective compliance program.

151. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica Inc. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal

³⁴ <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last visited May 30, 2017).

place of business in Titusville, New Jersey. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc.'s stock, and it corresponds with the FDA regarding Janssen's products. Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceutical's drugs, and Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson collectively are referred to herein as "Janssen."

152. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Coos County and the rest of the nation, including Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

153. Until January 2015, Janssen also developed, marketed, and sold Nucynta and Nucynta ER:

- a. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

- b. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the “relief of moderate to severe acute pain in patients 18 years of age or older.”

154. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.³⁵ Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

155. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. collectively are referred to herein as “Endo.”

156. Endo develops, markets, and sells prescription drugs, including the following opioids, in Coos County:

- a. Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Opana ER was indicated for the “relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.”

³⁵ <http://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html> (last visited May 31, 2018).

- b. Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the “relief of moderate to severe acute pain where the use of an opioid is appropriate.”
- c. Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the “management of moderate to moderately severe pain.”
- d. Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the “relief of moderate to moderately severe pain.”³⁶

157. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and alone accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids in Coos County, both itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

158. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in March 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013 and then to Actavis plc in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson

³⁶ In addition, Endo marketed Zydene (hydrocodone bitartrate and acetaminophen), a Schedule III opioid agonist tablet indicated for the “relief of moderate to moderately severe pain,” from 1998 through 2013. The FDA’s website indicates this product is currently discontinued, but it appears on Endo’s own website.

Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as “Actavis.”

159. Actavis engages in the business of marketing and selling opioids in Coos County and across the country, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian (morphine sulfate extended release) is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Prior to April 2014, Kadian’s indication was limited to the “management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.” Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008, and began marketing Kadian in 2009.

160. Mallinckrodt LLC (“Mallinckrodt”) is a Delaware corporation with its principal place of business in Hazelwood, Missouri.

161. Mallinckrodt develops, markets, and sells prescription drugs, including oxycodone, in Coos County.

2. Distributor Defendants.

162. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California.

163. Defendant McKesson had a net income in excess of \$1.5 billion in 2015.

164. Defendant McKesson distributes pharmaceuticals to retail pharmacies and institutional providers to customers in New Hampshire and Coos County. Upon information and belief, Defendant McKesson is a pharmaceutical distributor licensed to do business in New Hampshire.

165. Defendant McKesson is the largest pharmaceutical distributor in North America. Upon information and belief, McKesson delivers one-third of all pharmaceuticals used in North America.

166. Defendant McKesson does substantial business in the State of New Hampshire and Coos County.

167. Defendant Cardinal Health Inc. (“Cardinal”) is an Ohio corporation with its principal place of business in Dublin, Ohio.

168. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in New Hampshire and Coos County.

169. Upon information and belief, Defendant Cardinal is a pharmaceutical distributor licensed to do business in New Hampshire. Defendant Cardinal does substantial business in the State of New Hampshire and Coos County.

170. Upon information and belief, Defendant Cardinal is one of the largest distributors of opioid pain medications in the State of New Hampshire.

171. Upon information and belief, Defendant AmerisourceBergen Corporation (“Amerisource”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

172. Defendant Amerisource does substantial business in the State of New Hampshire and Coos County. Upon information and belief, Defendant Amerisource is a pharmaceutical distributor licensed to do business in the State of New Hampshire.

173. Defendant Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in New Hampshire and Coos County.

174. Upon information and belief, Defendant Amerisource is one of the largest distributors of opioid pain medications in the country, including the State of New Hampshire and Coos County.

175. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Coos County.

3. Defendant Retail Pharmacies.

176. Defendant CVS Health Corporation (“CVS”) is a Delaware Corporation with its principal place of business in Rhode Island.

177. At all times relevant to this Complaint, CVS distributed prescription opioids throughout New Hampshire and in Coos County.

178. Defendant CVS distributes pharmaceuticals to retail pharmacies and institutional providers to customers in Coos County and throughout New Hampshire.

179. Defendant CVS does substantial business in Coos County and throughout New Hampshire.

180. Upon information and belief, defendant CVS is one of the largest distributors of opioid pain medications in Coos County and throughout New Hampshire.

181. Defendant Rite Aid of Maryland, Inc. dba Rite Aid Mid-Atlantic Customer Support Center, Inc. (“Rite Aid”) is a Maryland Corporation with its principal office located in Camp Hill, Pennsylvania. It has multiple highly profitable locations in Coos County and throughout New Hampshire that bring in millions of dollars of profit and is a lead seller of pharmaceutical drug sales.

182. At all times relevant to this Complaint, Rite Aid distributed millions of dollars of prescription opioids in Coos County and throughout New Hampshire.

183. Defendant Rite Aid distributes pharmaceuticals to retail pharmacies and institutional providers to customers in Coos County and throughout New Hampshire.

184. Defendant Rite Aid does substantial business in Coos County and throughout New Hampshire.

185. Upon information and belief, Defendant Rite Aid is one of the largest distributors of opioid pain medications in Coos County and throughout New Hampshire.

186. Defendant Walgreens Boots Alliance, Inc., also known as Walgreen Co. (“Walgreens”) is a Delaware Corporation with its principal office located in Illinois and with multiple highly profitable locations in Coos County and throughout New Hampshire that bring in millions of dollars of profit and is a lead seller of pharmaceutical drug sales.

187. At all times relevant to this Complaint, Walgreens distributed prescription opioids in Coos County and throughout New Hampshire.

188. Defendant Walgreens distributes pharmaceuticals to retail pharmacies and institutional providers to customers in Coos County and throughout New Hampshire.

189. Defendant Walgreens does substantial business in Coos County and throughout New Hampshire.

190. Upon information and belief, defendant Walgreens is one of the largest distributors of opioid pain medications in Coos County and throughout New Hampshire.

191. Defendant Walmart Inc. formerly known as Walmart Stores, Inc. (“Walmart”) is a Delaware Corporation with its principal office located in Arkansas and with multiple highly profitable locations in Coos County and throughout New Hampshire that bring in millions of dollars of profit and is a lead seller of pharmaceutical drug sales.

192. At all times relevant to this Complaint, Walmart distributed prescription opioids in Coos County and throughout New Hampshire.

193. Defendant Walmart distributes pharmaceuticals to retail pharmacies and institutional providers to customers in Coos County and throughout New Hampshire.

194. Defendant Walmart does substantial business in Coos County and throughout New Hampshire.

195. Upon information and belief, defendant Walmart is one of the largest distributors of opioid pain medications in Coos County and throughout New Hampshire.

4. Individual Defendants.

196. Dr. Michael P. Dipre, M.D., is an individual with an office at 724 N. Main St., Laconia, Belknap County, New Hampshire 03894. Defendant Dr. Dipre has been disciplined on multiple occasions for improper prescribing of opioids, due to overprescribing and improper maintenance of records indicating why these high volumes were prescribed.³⁷ Dr. Dipre was

³⁷ <https://www.oplc.nh.gov/medicine/documents/20081022-michael-p-dipre.pdf>.

instrumental in promoting opioids for sale and dissemination in Coos County and throughout New Hampshire.

197. Dr. Mark D. Weinreb, M.D., is an individual with an office at 125 S Main St, Franklin, Merrimack County, New Hampshire 03235. Dr. Weinreb was a pediatric psychologist before his license was suspended and his prescriptions were questioned by another pediatric psychiatrist with mutual patients who noticed issues with the amount and types of medications he was prescribing. Dr. Weinreb's prescribing of opioids "to numerous patients fell below the standard of care. He prescribed excessive amounts of narcotics to pediatric patients without documenting his rationale. He repeatedly refilled prescriptions for narcotics without examining patients."³⁸ In one instance, Dr. Weinreb prescribed over 2,000 tablets of oxycodone to a single child in an eleven-month period, which would have been fatal if taken as prescribed. This patient's sibling was prescribed 1,200 tablets of oxycodone in a ten-month period. Dr. Weinreb also failed to properly document prescriptions for opioids. On December 7, 2012, Dr. Weinreb's license was revoked for a period of five years from his original date of suspension in January 2012, after which time he could re-apply for licensure. Dr. Weinreb was instrumental in promoting opioids for sale and dissemination in Coos County and throughout New Hampshire.

198. Christopher Clough is an individual residing in Dover, Strafford County, New Hampshire. Mr. Clough was arrested in March 2017 on charges he received kickbacks in exchange for prescribing fentanyl spray to patients. Clough worked as a physician assistant. According to the indictment, "from approximately mid-2013 through Fall 2014, Clough wrote more than 700 prescriptions for the fentanyl spray in New Hampshire, including more than 200 prescriptions for Medicare patients. During that time, the manufacturer of the drug paid Clough

³⁸ <https://www.oplc.nh.gov/medicine/documents/20121207-mark-weinreb.pdf>.

purportedly to serve as a speaker at more than 40 programs at a rate of approximately \$1,000 per event. In many instances, the programs were merely sham events where Clough was paid to have dinner with employees or representatives of the pharmaceutical company. In other instances, the programs were attended by individuals, including colleagues and friends, who were not authorized to prescribe controlled substances. For the majority of these dinner programs, the indictment alleges that Clough did not give any kind of presentation about the drug at all. Clough and others often forged signatures of attendees on sign-in sheets in an effort to make the dinners appear to be legitimate. The indictment alleges that the speaking program payments existed primarily to reward Clough for writing substantial numbers of prescriptions and to create an incentive for him both to issue new prescriptions and to increase dosages on existing prescriptions. From August 2013 until October 2014, Clough was paid more than \$41,000 by the drug manufacturer.”³⁹ Mr. Clough was instrumental in promoting opioids for sale and dissemination in Coos County and New Hampshire.

199. Eric L. Knight, M.D., is an individual with an address at 19 Elm St., Keene, Sullivan County, New Hampshire 03431. Until his termination on June 20, 2017, Defendant Dr. Knight was employed as a family practice physician at Valley Regional Hospital in Claremont, Sullivan County, New Hampshire. Dr. Knight’s license to practice medicine was suspended by the New Hampshire Board of Medicine in September 2017 for violating laws regarding opioid prescribing and admitting that he did not pay attention to the Board’s rules regarding the same. Dr. Knight “violated Med 502, the state Board of Medicine’s rules for prescribing controlled substances and the AMA’s principles of medical ethics when he failed to use ‘pain contracts’ with 85 of the 87 patients for whom he had prescribed opioids in the previous year.”⁴⁰ He also

³⁹ <https://www.justice.gov/usao-nh/pr/former-physician-assistant-charged-healthcare-kickback-scheme>.

⁴⁰ <https://www.vnews.com/New-Hampshire-Board-of-Medicine-Suspends-License-of-Former-Valley-Regional-Doctor-12742669>.

prescribed opioids at amounts far exceeding recommended doses and without using the Prescription Drug Monitoring Program. Dr. Knight was instrumental in promoting opioids for sale and dissemination in Coos County and throughout New Hampshire.

5. Additional Purdue Defendants.

200. Defendant Richard S. Sackler is a natural person residing in Florida. He is a son of Purdue founder Raymond Sackler.

201. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is a son of Raymond Sackler.

202. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler.

203. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Purdue founder Mortimer Sackler.

204. Defendant Kathe Sackler a natural person residing in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler.

205. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler.

206. Defendant Theresa Sackler is a natural person residing in the United Kingdom. She is the widow of Mortimer Sackler.

207. Defendant David Sackler is a natural person residing in Florida. He is the son of Richard S. Sackler and grandson of Raymond Sackler.

208. Defendants Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler and Theresa Sackler have served as members of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

209. Defendant David Sackler became a board member of Purdue Pharma Inc. in 2012.

210. In addition to the foregoing members of the Sackler family (the “Sackler Family Defendants”), Defendants Cecil Pickett, Paulo Costa, Ralph Snyderman, and Peter Boer are also board members of Purdue Pharma Inc. and Defendant Judy Lewent is a prior board member (the “Additional Purdue Board Member Defendants”).

211. Defendant Cecil Pickett is a natural person residing in New Jersey. Pickett joined the Board in 2010.

212. Defendant Paulo Costa is a natural person residing in Connecticut. Costa joined the Board in 2012.

213. Defendant Ralph Snyderman is a natural person residing in North Carolina. Snyderman joined the Board in 2012.

214. Defendant Frank Peter Boer (“Peter Boer”) is a natural person residing in Florida. Boer joined the Board in 2013

215. Defendant Judy Lewent is a natural person residing in New Jersey. Lewent was on the Board at least from 2009 to 2014.

216. The Sackler Family Defendants and the Additional Purdue Board Member Defendants are collectively referred to as the “Purdue Board Defendants.”

217. Since June 2007, there have been three Chief Executive Officers of Purdue Pharma Inc. and Purdue Pharma L.P.: John Stewart, Mark Timney and Craig Landau (the “Purdue CEO Defendants”).

218. Defendant John Stewart was Chief Executive Officer from 2007 to 2014. He is a natural person residing in Florida.

219. Defendant Mark Timney was Chief Executive Officer from 2014 to June 2017. He is a natural person residing in Connecticut.

220. Defendant Craig Landau has been the Chief Executive Officer of Purdue Pharma Inc. and Purdue Pharma L.P. since June 2017. He is a natural person residing in Connecticut.

221. Defendant Russell Gasdia was Vice-President of Sales and Marketing for Purdue Pharma Inc. and Purdue Pharma L.P. He is a natural person living in Massachusetts.

222. Each of the foregoing individual Additional Purdue Defendants are referred to collectively as the Individual Purdue Defendants and are included collectively in the allegations relating to the “Purdue” entities and collectively in the complaint’s allegations, claims and causes of action as a “Manufacturer Defendant.”

223. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the “Raymond Sackler Trust”) is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. Upon information and belief, it is the 50% direct or indirect beneficial owner of Purdue and the Additional Purdue Defendants and the recipient of 50% of the profits from the sale of opioids by Purdue.

224. Defendant The P.F. Laboratories, Inc. (“PF Labs”) is a New Jersey corporation with its principal place of business located in Totowa, New Jersey. It was, at relevant times, engaged in the business of manufacturing OxyContin for Purdue. At all relevant times, PF Labs has been beneficially owned, managed, and controlled by Defendant Sackler Family members.

225. The Raymond Sackler Trust and PF Labs are included collectively in the term “Purdue” and collectively in the complaint’s allegations, claims and causes of action as a “Manufacturer Defendant.”

226. It is believed that additional parties participated and aided and abetted in the wrongful conduct alleged herein but their identities or nature or extent of unlawful participation are as yet unknown. For ease of reference, they can only be referred to herein at this time as Doe Defendants.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. Background on Pain Medicine.

1. Safe and Effective Treatment of Chronic Pain Centers on Informed Risk Management.

227. The practice of medicine centers on informed risk management. Each prescriber must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment.

228. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment; and (b) the risks and benefits of alternatives.

229. This bedrock principle of full disclosure is critical in the context of chronic opioid therapy because of the risk that patients will become physically or psychologically dependent on the drugs.

230. Patients who become physically or psychologically dependent on the drugs find it difficult or impossible to manage or terminate their use.

231. The pull of addiction to Defendants' opioid products is so strong that a significant number falter, and many who falter, and their families, become an economic burden. As a direct and proximate result of Defendants' misconduct as referenced herein, the taxpayers of Coos County have wrongfully been forced to carry that cost

232. The FDA-approved drug labels on each of Manufacturer Defendants' opioids do not attempt to advise physicians how to maximize the benefits and minimize the risks for patients on long-term chronic opioid therapy.

233. Manufacturer Defendants' opioids labels do not contain a dosing cap, above which it would be unsafe or risky for any doctor to prescribe to any patient.

234. Manufacturer Defendants' opioids labels do not provide a duration limit, after which the risks to a patient might increase. Doctors and patients rely more heavily on educational materials such as treatment guidelines, CMEs, and scientific and patient education articles and websites to inform their treatment decisions.

2. Opioid Use Is Associated with Known and Substantial Risks.

235. Opium has been recognized for its potential for abuse, addiction and related dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

236. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield. They were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages.

237. By 1900, an estimated 300,000 people were addicted to opioids in the United States.⁴¹ Many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

⁴¹ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

238. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration (“DEA”) since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “serious, life-threatening, or fatal respiratory depression,” as the result of an excessive dose.

239. Studies and articles from the 1970s and 1980s also made reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids’ mixed record in reducing pain long-term and failure to improve patients’ function; greater pain complaints as most patients developed tolerance to opioids; opioid patients’ diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

240. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms.

241. The withdrawal symptoms caused by discontinuing opioids after more than just a few weeks of therapy include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. Some symptoms may persist for months after a complete withdrawal from opioids.

242. Patients grow tolerant to the analgesic effects of opioids over time. As tolerance increases, patients typically require progressively higher doses to obtain the same levels of pain reduction to which they become accustomed, including doses that are “frighteningly high.”⁴²

⁴² M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med. 1422 (2010).

243. As doses get higher, so do the effects of opioid withdrawal and so do the risks to which the patients are subject. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and overdose at recommended levels.

244. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to “hijack[ing] the brain’s reward system,” which in turn convinces a user that “the drug is needed to stay alive.”⁴³ A patient’s fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

245. Patients that receive high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses.

246. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Again, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to an overdose even when opioids are taken as recommended.

247. Further, “a potential side effect from chronic use [of opioids] can be abuse and addiction . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena.”⁴⁴

⁴³ David Montero, *Actor’s Death Sows Doubt Among O.C.’s Recovering Opioid Addicts*, The Orange Cnty. Reg. (Feb. 3, 2014), <http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html>.

⁴⁴ Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (2006).

248. It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

249. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.⁴⁵

250. Each of these risks and adverse effects—dependence, tolerance, and addiction—is fully disclosed in the labels for each of Defendants’ opioids (though, as described below, not in Defendants’ marketing).⁴⁶

251. Prior to Manufacturer Defendants’ unfair, deceptive or unlawful Marketing Efforts, each of these risks was accepted by doctors.

252. In fact, prior to Manufacturer Defendants’ unfair, deceptive or unlawful Marketing Efforts, the risks were seen as a reason to sparingly use opioids to treat chronic pain. The use of opioids was typically only employed after other treatments had failed.

253. Opioids vary by duration. Long-acting opioids, such as Purdue’s OxyContin and MS Contin, Janssen’s Nucynta ER and Duragesic, Endo’s Opana ER, and Actavis’s Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. The length of duration was misrepresented by Manufacturer Defendants.

⁴⁵ Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) *Addiction* 1776 (2010); Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) *Journal of Addictive Diseases* 185 (2011).

⁴⁶ For example, Purdue’s OxyContin label (Oct. 5, 2011) states: “Physical dependence and tolerance are not unusual during chronic opioid therapy.”

254. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

255. Manufacturer Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them with short-acting, rapid-onset opioids for episodic pain.

256. Despite actual knowledge that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, Defendants promoted this view until it was thoroughly discredited by third parties.

257. Only now, after the crisis artificially created by the Defendants' wrongful conduct has devastated Coos County did OxyContin's label state that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death."

258. At this time, many labels of Schedule II long-acting opioids suggest that the product exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death.

259. This is only because the FDA eventually required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."⁴⁷

260. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death."⁴⁸

⁴⁷ FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids* (last updated Oct. 9, 2014), <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>.

⁴⁸ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

261. The FDA further warned that “even proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death.”⁴⁹

262. In 2013, and at least in part in response to the growing opioid epidemic created by Manufacturer Defendants’ willful and knowing Marketing Efforts, the FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels.

263. In 2013, the FDA restated what had been the accepted practice for the treatment of pain prior to Defendants’ willful and knowing, unfair, deceptive or unlawful Marketing Efforts. More specifically, that the adverse outcomes from opioid use include “addiction, unintentional overdose, and death” and, that long-acting or extended release opioids “should be used *only when alternative treatments are inadequate*.”⁵⁰

264. It is noteworthy that in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

265. The FDA-approved labels on each of Manufacturer Defendant’s opioids do not attempt to advise physicians on how to maximize the benefits and minimize the risks for patients on long-term opioid therapy.

266. The FDA-approved labels on each of Manufacturer Defendant’s opioids still do not contain a dosage cap above which it would be unsafe to prescribe to any patient.

267. The FDA-approved labels on each of Manufacturer Defendant’s opioids do not provide a duration limit. Doctors and patients must rely heavily on the education materials, such

⁴⁹ *Id.*

⁵⁰ *Id.* at 7 (emphasis in original).

as treatment guidelines, CMEs, and scientific and patient education articles and websites provided through Manufacturer Defendants' Marketing Efforts to inform their treatment decisions.

268. On July 25, 2012, the Physicians For Responsible Opioid Prescribing ("PROP"), a non-profit organization made up of doctors and other health care professionals, petitioned the FDA to change the labeling of opioid medications. The PROP petition was signed by thirty-seven physicians located nationwide. The PROP letter to the FDA stated that "an increasing body of medical literature suggests that long term-use of opioids may be neither safe nor effective for many patients, especially when prescribed in high doses."⁵¹

269. In its petition, PROP also stated that "many clinicians are under the false impression that chronic opioid therapy ("COT") is an evidence-based treatment for chronic non-cancer pain" and that "these misconceptions lead to overprescribing and high dose prescribing." It was also their opinion that "the current label on opioid analgesics does not comply with [FDA law]."

270. In support of its petition, PROP provided "Statements of Scientific Basis for Petition" which provided a list of detailed reports and studies proving the risks of opioid medications, the high risk of addiction, the exaggerated and false benefits, and further medically backed reasons to change the labelling of opioid medications to reduce prescribing.

271. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional

⁵¹ July 25, 2012 letter from PROP to FDA, *available at* <http://www.citizen.org/documents/2048.pdf> on May 17, 2017.

safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.⁵²

272. Manufacturer Defendants had actual knowledge of the facts on which the FDA relied in 2013 and 2016 were false, deceptive and misleading.

3. Long-Term Opioid Use Benefits Are Unproven and Contradicted.

273. Manufacturer Defendants' Marketing Efforts ran counter to the truth that there has never been evidence of their safety and efficacy for long-term use. Only as a direct and proximate result of such Defendants' Marketing Efforts are opioids are now routinely prescribed.

274. At all times relevant to this complaint, Manufacturer Defendants were aware that the representations made through their Marketing Efforts were unsupported and ran counter to the credible available data.

275. At all times relevant to this complaint, Manufacturer Defendants failed to disclose the lack of evidence to support their long-term use and otherwise failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker while promoting opioids to treat chronic pain. Instead they willfully misrepresented the truth to drive their sales volumes, and profits, up.

276. There are no controlled studies of the use of opioids beyond sixteen weeks.

277. There is no evidence that opioids improve patients' pain and long-term function.

278. The first random, placebo-controlled studies appeared in the 1990s.

⁵² FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. *available at* <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm> (last visited May 31, 2018).

279. Those studies concluded that the evidence supported only short-term efficacy in only a minority of patients.⁵³ In the face of these results, Defendants continued to misrepresent the truth.

280. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes.

281. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.

282. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor.

283. One year later, in 2012, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

284. In stark contrast to Manufacturer Defendants' Marketing Efforts, evidence existed to show that opioid drugs are not effective to treat chronic pain and may worsen patients' health.

285. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most

⁵³ Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

notably, it stated: “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”⁵⁴

286. Another review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

287. Defendant Endo’s own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%). All Manufacturer Defendants have actual knowledge of the same or similar findings and conclusions. Also, increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization. Despite the actual knowledge of the risks and devastating effects of opioids and the artificial epidemic they created as referenced herein, Defendants manufactured studies and marketing materials that contained false and misleading information and data throughout this period considered in the instant civil action.

288. As noted in an article authored by a pain specialist and titled *Are We Making Pain Patients Worse?*, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function

⁵⁴ Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass’n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass’n 940 (2012).

normally.”⁵⁵ The conclusion that over the long term, function generally declines, as does general health, mental health, and social functioning, is true both generally and for specific pain-related conditions.

289. Studies of the use of opioids long-term for chronic lower back pain have not demonstrated an improvement in patients’ function. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

290. Notably, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches and users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.

291. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

292. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers’ compensation claims, where some of the most detailed data exists.

293. Claims involving workers who take opioids are almost four times as likely to reach costs of over \$100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the

⁵⁵ Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

4. Manufacturer Defendants' Impact on the Perception and Prescribing of Opioids.

294. As referenced above, before Manufacturer Defendants began their fraudulent or misleading Marketing Efforts, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care.

295. In 1986, the World Health Organization (the "WHO") published an "analgesic ladder" for the treatment of cancer pain.⁵⁶ The WHO recommended treatment with over-the-counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, and then the use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted.

296. The 1986 WHO analgesic ladder for the treatment of cancer pain pertained only to the treatment of cancer pain and did not contemplate the use of narcotic opioids for chronic pain. This was at least in part because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

297. Studies and articles from the 1970s and 1980s made the reasons to avoid opioids clear. At least in part, scientists observed negative outcomes from long-term opioid therapy in pain management programs including:

- a. opioids' mixed record in reducing pain long term and failure to improve patients' function;
- b. greater pain complaints as most patients developed tolerance to opioids;

⁵⁶ http://apps.who.int/iris/bitstream/10665/43944/1/9241561009_eng.pdf (last visited May 31, 2018).

- c. opioid patients' diminished ability to perform basic tasks;
- d. their inability to make use of complementary treatments, like physical therapy, due to the side effects of opioids;
- e. addiction; and
- f. leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

298. In 1986, Defendants' Key Opinion Leader Dr. Russell Portenoy published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."⁵⁷ This report was false and misleading and both Dr. Portenoy and Defendants had actual knowledge of its falsity.

299. Dr. Portenoy later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies.

300. In 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain*

⁵⁷ Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

*analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*⁵⁸

301. According to Portenoy, these problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”⁵⁹

302. For the reasons outlined by Dr. Portenoy, and in the words of one researcher from the Harvard Medical School, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids.”⁶⁰

303. Portenoy’s unscrupulous efforts were part of the Defendants’ marketing plan. The Defendants’ unfair, deceptive or unlawful Marketing Efforts, including Dr. Portenoy’s unscrupulous efforts, were intended to, and did, change that perception within the medical community and beyond patients and medical health providers.

B. Manufacturer Defendants Promoted Their Branded Products Through Direct Marketing to Prescribers and Consumers.

304. Manufacturer Defendants’ Marketing Efforts proceeded on two tracks, each serving two related purposes.

305. First, Manufacturer Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by falsely overstating its benefits and downplaying its risks, thereby expanding the chronic pain market.

⁵⁸ Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994) (emphasis added).

⁵⁹ *Id.*

⁶⁰ Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012).

306. Second, Manufacturer Defendants worked through their own staff sales representatives, physician speakers (whom those staff representatives recruited), and advertising in medical journals to claim their share of that broader market.

307. Manufacturer Defendants unscrupulously and unlawfully directed all of this activity through carefully designed Marketing Efforts and plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

1. Manufacturer Defendants Employed and Relied Upon Branded Advertisements.

308. Manufacturer Defendants engaged in widespread unlawful advertising campaigns in furtherance of the Marketing Efforts, falsely touting the benefits of their branded drugs. For example, Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*.

309. The advertising budgets that propelled Manufacturer Defendants' unfair, deceptive and unlawful Marketing Efforts increased in 2011, when they collectively spent more than \$14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.⁶¹

310. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. For example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period

⁶¹ Actavis' and Cephalon's medical journal advertising peaked earlier, with Actavis spending \$11.7 million in 2005, and Cephalon spending about \$2 million in each of 2007 and 2008.

of time.” The advertisement featured a man and boy fishing and proclaimed that “There Can Be Life With Relief.”

311. The aforementioned depiction was intended to, and did, falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

2. Manufacturer Defendants Relied Upon Their Sales Forces and Recruited Physician Speakers.

312. Each Manufacturer Defendant intended to, and did, deceptively promote the use of opioids for chronic pain through “detailers”— sales representatives (the “Detailers”). The Detailers were intended to, and did, visit individual physicians and their staff in their offices—and small group speaker programs for the purpose of establishing close relationships with doctors. The close relationships created were intended to, and did, allow for the Manufacturer Defendants’ sales representatives to disseminate their misrepresentations in targeted, one-on-one settings that increased the effectiveness of their efforts to falsely differentiate their opioids and to address individual prescribers’ concerns about prescribing opioids for chronic pain. The Detailers were trained to employ unscrupulous and deceptive techniques to build these relationships, with Actavis even rolling out an “Own the Nurse” kit as a “door opener” to time with doctors.

313. Manufacturer Defendants also developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Manufacturer Defendants purchased and closely analyzed prescription sales data from IMS Health. That data allowed them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allowed them to target, tailor, and monitor the impact of their appeals.

314. Manufacturer Defendants, in particular, relied upon “influence mapping,” *i.e.*, using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact. Endo, for example, identified prescribers representing 30% of its nationwide sales volume and planned to visit these physicians three times per month. Manufacturer Defendants also closely monitored doctors’ prescribing after a sales representative’s visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

315. Manufacturer Defendants’ sales representatives have visited hundreds of thousands of doctors, including thousands of visits to Coos County prescribers and prescribers in the surrounding areas. As described herein, Manufacturer Defendants’ Marketing Efforts were intended to, and did, spread misinformation regarding the risks, benefits, and (purported) superiority of opioids for the treatment of chronic pain. Manufacturer Defendants’ misinformation also included deceptive and unfair claims relating to the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

316. In carrying out its Marketing Efforts, each Manufacturer Defendant unfairly, deceptively and unlawfully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company’s drugs specifically, and opioids in general. Upon information and belief, the marketing departments, not the science, medicine or other non-sales data drove the message, content, focus and target market.

317. Manufacturer Defendants exactly directed and monitor their Detailer sales representatives. The Marketing Efforts included detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means. The detailed Marketing Efforts were designed

to ensure that individual Detailers actually deliver the desired messages and would not veer off-script.

318. Manufacturer Defendants likewise required their Detailers to deploy sales aids reviewed, approved, and supplied by the company and forbid them to use, in industry parlance, “homemade bread”—*i.e.*, promotional materials not approved by the company’s marketing and compliance departments. Adherence to corporate training is typically included in the work agreements of the Manufacturer Defendants’ sales representatives. It is also standard industry practice for Manufacturer Defendants to impose severe consequences, including termination of employment, whenever they learn a Detailer departs from company approved messaging can.

319. In addition to the strict training and monitoring of Detailers, Manufacturer Defendants used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers.

320. Manufacturer Defendants’ Detailers were required to identify doctors to serve, for payment, on Defendants’ speakers’ bureaus.

321. Manufacturer Defendants’ Detailers were required to attend programs with speakers and meals paid for by Defendants.

322. Manufacturer Defendants’ Detailers almost always selected physicians who were “product loyalists”.

323. Endo, for instance, sought out physicians who specialized in pain management medicine and other high prescribers of its drugs to serve as local “Thought Leaders” (together “Marketing M.D.”). A focus of the Thought Leaders was to market Opana to emergency room and primary care doctors.

324. Being invited to serve as speakers, Thought Leaders or other Marketing Effort positions are lucrative to the physicians selected. Honorarium rates range from \$800 to \$2,000 per program, depending on the type of event, and even speaker training is typically compensated at \$500 per hour.

325. The Marketing Effort speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase, their prescriptions of, a particular drug; a forum in which to further market to the speaker him or herself; and an opportunity to market to the speaker's peers.

326. Manufacturer Defendants graded their Marketing M.D. speakers according to criterion that were sales generation based, and future opportunities were based on speaking performance, post-program sales, and product usage. Endo noted that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before."

327. Manufacturer Defendants also tracked the prescribing record of each event attendee.

328. It is noteworthy that the Marketing M.D.s were subjected to the same level of content and opinion control as the Detailers. Like the unlicensed sales representatives who selected them, the medical doctor speakers were required to stay "on message" and homemade bread was forbidden.

329. Moreover, the Marketing M.D.'s agreed in writing to follow the slide decks provided to them. Endo's speaker rules, for example, provide that "all slides must be presented in their entirety and without alterations . . . and in sequence."

330. This is noteworthy because the FDA considers promotional talks a part of product labeling and requires their submission for review.

331. Speakers were trained and otherwise gave the appearance of providing an independent, unbiased presentations on opioids, when in fact they presented false and deceptive Marketing Efforts, including, but not limited to, designed scripts prepared by Manufacturer Defendants' marketing departments. Although these meal-based speaker events are more expensive to host, and typically have lower attendance than CMEs, they are subject to less professional scrutiny and afforded Defendants greater freedom in the messages they present. Defendants exploited these opportunities.

332. Manufacturer Defendants devoted massive resources to the direct sales contacts with prescribers referenced herein.

333. In 2014, Manufacturer Defendants collectively spent \$168 million on detailing branded opioids to physicians nationwide. This figure includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Actavis. That total figure is more than double Manufacturer Defendants' collective spending on detailing in 2000.

334. Manufacturer Defendants' Detailers' role in overall promotional efforts was also carefully calibrated. Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

335. Defendant Pharmaceutical Companies have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they established through internal data that the detailers' sales pitches are effective.

336. Numerous studies indicate that marketing can and does impact doctors' prescribing habits,⁶² and that face-to-face detailing has the highest influence on intent to prescribe.

337. Manufacturer Defendants tracked and exploited this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers whom they targeted for detailing, and who responded by prescribing more of such Defendants' drugs.

3. Manufacturer Defendants Directed These Promotional Efforts Through Detailed Marketing Plans.

338. Manufacturer Defendants strictly designed, guided and monitored all efforts to expand opioid prescribing through unfair, deceptive or unlawful comprehensive marketing and business plans for each drug. These documents were based on extensive market research and included detailed ambitious plans designed to bring in new prescribers and increase overall prescribing of such Defendants' opioids.

a. Targeting categories of prescribers

339. Manufacturer Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing.

340. Manufacturer Defendants chose their targets based on the potential for persuading a provider to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses.

⁶² See, e.g., Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15(2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

341. The targeting of prescribers was not correlated to demonstrated need or demand for opioid therapy.

342. The targeting of prescribers was not correlated to risk of abuse.

343. Collectively, Manufacturer Defendants' marketing plans establish dual strategies, which often operated parallel to one another.

344. First, Manufacturer Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists because they were, and continue to be the highest-volume prescribers of opioids. Additionally, as a group pain specialists and anesthesiologists are more educated than other practitioners about opioids' risks and benefits.

345. Second, Manufacturer Defendants targeted increasing numbers and types of prescribers for marketing ("Expanded Market"). Manufacturer Defendants did this to develop market share and expand sales of opioids and not in response to a scientifically sound medical need.

346. Manufacturer Defendants' market research concluded that Expanded Market prescribers were more susceptible to Defendants' marketing messages.

347. The Expanded Market prescribers eventually included nurse practitioners and physician assistants.

348. The Expanded Market prescribers also included internists and general practitioners who were low- to mid-volume prescribers.

349. Manufacturer Defendants knew that the aforementioned Expanded Market prescribers, as a group, were less informed about opioids. Thus, Manufacturer Defendants targeted the Expanded Market prescribers for exploitation.

350. A 2012 Endo business plan noted that the Expanded Market prescribers were “share acquisition” opportunities because they were “3x times more responsive than MDs to details” and wrote “96% of [their] prescriptions . . . without physician consult.”

351. Actavis rolled out a plan in 2008 to move beyond “Kadian loyalists” to an “expanded audience” of “low morphine writers.”

b. Increasing “direct to consumer” marketing

352. Manufacturer Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications.

353. Endo’s research, for example, found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations. Such Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician’s office, as well as employer and workers’ compensation plan initiatives to, as Endo put it, “[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss.”

354. Manufacturer Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor’s drug—was out-of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Manufacturer Defendants did so through vouchers and coupons distributed during detailing visits with prescribers.

355. A 2008 Actavis business review, for example, highlighted co-pay assistance, good for up to \$600 per patient per year, as a way to drive conversions to Kadian from competitor drugs

like Avinza and MS Contin. In 2012, Janssen planned to distribute 1.5 million savings cards worth \$25 each.

c. Differentiating each brand

356. By 2010, Manufacturer Defendants had begun facing increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse.

357. Purdue's OxyContin was the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012.

358. Both aforementioned market conditions prompted some of the remaining Manufacturer Defendants to pursue product differentiation strategies.

359. More specifically, they placed an emphasis on their products being less subject to diversion, abuse, and addiction as a means of grabbing market share from Purdue and other competitors.

360. Endo, for example, tracked in detail prescriber "switching" from OxyContin to Opana ER.

361. Actavis and Janssen did the same for switches to Kadian and Nucynta ER, respectively.

362. Pressure to stand out among other drugs resulted in Manufacturer Defendants identifying marketing themes that thereafter were reflected in such Defendants' deceptive and harmful messages to physicians and consumers.

363. A 2008 Janssen plan emphasized "value" messaging in support of Nucynta ER, including claims of less dose escalation, fewer withdrawal symptoms, and less dependence.

364. A 2009 Opana ER market research report focused on greater potency and lower abuse potential of Opana ER vis-à-vis OxyContin.

d. Moving beyond office visits

365. Manufacturer Defendants also sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. These new channels included sales forces' Marketing Efforts directed to prescribers through voice mail, postcards, and email—so-called “e-detailing.”

366. Manufacturer Defendants also created new Marketing Efforts' platforms for their speakers. These Marketing Efforts included implementing “peer to peer” programs such as teleconferences and webinars that were available to prescribers in New Hampshire.

367. The new Marketing Effort programs allowed Manufacturer Defendants to use this more, seemingly credible, vehicle to market to hard-to-reach audiences such as prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person detailing.

368. Manufacturer Defendants relied heavily on speakers to promote their drugs as they employed these new approaches to its unfair, deceptive or unlawful Marketing Efforts.

Manufacturer Defendants Marketed Opioids in Coos County Using the Same Strategies and Messages They Employed Nationwide.

369. Manufacturer Defendants employed the same unfair, deceptive or unlawful Marketing Efforts in Coos County as they did nationwide.

370. Manufacturer Defendants employed the same unfair, deceptive or unlawful strategies and deployed the same messages in Coos County as they did nationwide.

371. Across the pharmaceutical industry, “core message” development is funded and overseen in New Hampshire by corporate headquarters. This comprehensive approach ensures that Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory.

372. Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

373. Manufacturer Defendants ensured consistency for their unfair, deceptive or unlawful Marketing Efforts through:

- a. New Hampshire and regional sales representative training;
- b. New Hampshire training of local medical liaisons, *i.e* the company employees who respond to physician inquiries;
- c. centralized speaker training;
- d. a single set of visual aids;
- e. a single set of speakers slide decks;
- f. a single set of sales training materials; and
- g. New Hampshire-coordinated advertising.

374. In addition to the above, the sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks. Moreover, Manufacturer Defendants supervisors traveled with sales representatives and physician speakers periodically to check on their performance and compliance and make related reports to Manufacturer Defendants' management who, in turn, made related reports to the Executive Level.

375. Manufacturer Defendants extensively tracked the prescribing behavior of Coos County area health care providers and used that data to target their detailing and speaker-recruiting efforts.

376. Top prescribers were profiled at the County, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into

deciles. Defendant Manufacturers exploited this marketing data to further their unlawful marketing efforts.

377. Misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of the Manufacturer Defendants' marketing campaigns in Coos County.

C. Manufacturer Defendants Used "Unbranded" Marketing along with KOLs and Front Groups to Further Their Deceptive Marketing Efforts.

378. In addition to their direct Marketing Efforts, Manufacturer Defendants, used unbranded marketing as part of their New Hampshire marketing strategies for their branded drugs.

379. Unlike their branded Marketing Efforts in which they identified a specific medication and the condition it was approved to treat, Manufacturing Defendants' unbranded Marketing Efforts touted the benefits of opioids generally without naming a specific brand-name.

380. Manufacturer Defendants acted in concert with networks of third-party KOLs and Front Groups to disseminate their unbranded messages as part of their Marketing Efforts.

381. Manufacturer Defendants funded, directed, assisted, and encouraged the unbranded efforts and activities of the KOLs and Front Groups.

382. Manufacturer Defendants' unbranded marketing was exceptionally devious, deceptive, unfair and unlawful because it was intended to and did allow Manufacturer Defendants to evade the oversight of federal regulators and to expand their untrue or misleading messages unchecked.

383. At the same time, Manufacturer Defendants exercised substantial control over the content of the messages third parties generated and disseminated, and they distributed certain of those materials themselves.

384. As with their other unfair, deceptive or unlawful Marketing Efforts, Manufacturer Defendants' unbranded marketing willfully and knowingly created an appearance of independence and credibility. The appearance of independence and credibility was central to its effectiveness, but entirely fraudulent and undeserved.

1. The Manufacturer Defendants Used Unbranded Marketing to Evade Regulations and Consumer Protection Laws which Require Branded Marketing to Be Truthful, Balanced, and Supported by Substantial Evidence.

385. Drug companies that manufacture, market, or distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs.

386. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.⁶³

387. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

388. The Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded."

389. A pharmaceutical drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."⁶⁴

⁶³ 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

⁶⁴ 21 U.S.C. § 352.

390. “Adequate directions for use” are directions “under which the layman can use a drug safely and for the purposes for which it is intended.”⁶⁵

391. “Labeling” includes more than the drug’s physical label; it also includes “all . . . other written, printed, or graphic matter . . . accompanying” the drug, including promotional material.⁶⁶

392. The term “accompanying” is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.⁶⁷ The promotional materials of Manufacturer Defendants are part of their drugs’ labels.

393. The promotional materials of Manufacturer Defendants that are part of their drugs’ labels are required to be accurate, balanced, and not be misleading.

394. Labeling is misleading if:

- a. it is not based on substantial evidence;
- b. if it materially misrepresents the benefits of the drug; or
- c. if it omits material information about or minimizes the frequency or severity of a product’s risks.

395. “The most serious risks set forth in a product’s labeling are generally material to *any* presentation of efficacy.”⁶⁸

⁶⁵ 21 C.F.R. § 201.5.

⁶⁶ 21 U.S.C. § 321(m).

⁶⁷ *See id.*

⁶⁸ FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.

396. The FDA notes that “because people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included.”⁶⁹

397. Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance.

398. Promotion that fails to present the most important risks of the drug as prominently as its benefits is deceptive.

399. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug’s safety or efficacy or present conclusions that “clearly cannot be supported by the results of the study.”⁷⁰

400. Manufacturer Defendants must not make comparisons between their drugs and other drugs that represent or suggest that “a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.”⁷¹

401. While the FDA must approve a drug’s label, it is the drug company’s responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.⁷²

⁶⁹ *Id.*

⁷⁰ 21 C.F.R. § 99.101(a)(4).

⁷¹ 21 C.F.R. § 202.1(e)(6)(ii).

⁷² See 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6)(iii)(A-C) (allowing manufacturers to make changes that “strengthen . . . a warning, precaution, or adverse reaction” or “strengthen a statement about drug abuse, dependence, psychological effect, or overdosage”).

402. Promotional materials must be submitted to the FDA when they are first used or disseminated.

403. The FDA does not have to approve these materials in advance.

404. If, upon review, the FDA determines that materials marketing a drug are misleading, it may issue an untitled letter or warning letter.

405. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information.

406. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

407. The FDA has made clear that its promotional requirements apply to marketing both carried out by manufacturers as well as carried out on its behalf:

FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.

. . . .

Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.⁷³

408. The promotional activity can be branded or unbranded.

409. Unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment.

⁷³ FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, January 2014, at 1, 4, <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf>.

410. By using unbranded communications, drug companies can sidestep the extensive regulatory framework governing branded communications.

2. Manufacturer Defendants Disseminated Unbranded Information as part of the Marketing Efforts.

411. Manufacturer Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly and in unbranded marketing materials.

412. Manufacturer Defendants' Marketing Efforts specifically contemplated their use because they were outside FDA oversight.

413. Through unbranded materials, Manufacturer Defendants avoided disclosing their own knowledge of the risks, benefits and advantages of opioids, and presented information and instructions concerning opioids.

414. Manufacturer Defendants' own knowledge of the risks, benefits and advantages of opioids stood in stark contrast to the unbranded materials they used in their Marketing Efforts. In fact, the unbranded materials Manufacturer Defendants used were contrary to, or at best, inconsistent with information and instructions listed on such Defendants' branded marketing materials and drug labels.

415. Manufacturer Defendants had actual knowledge that that unbranded materials they caused to be disseminated to their target markets were not submitted to or reviewed by the FDA.

416. Even where such unbranded messages were channeled through third-party vehicles, Manufacturer Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials. At all times relevant to this action, Manufacturer Defendants knew the unbranded materials they caused to be disseminated to their target markets were false, misleading, unsubstantiated, unbalanced, and incomplete.

417. Manufacturer Defendants willfully used unbranded Marketing Materials to avoid review by the FDA, and this maneuver was a part of their Marketing Efforts.

418. Unbranded brochures and other materials that are “disseminated by or on behalf of [the] manufacturer” constitute drug “labeling” that may not be false or misleading in any particular. *See* 21 C.F.R. § 202.1(e)(7)(1)(2).⁷⁴

419. Manufacturer Defendants’ sales representatives distributed third-party marketing material that was deceptive to such Defendants’ target audiences and such Defendants are responsible for the damage caused in part by these materials.

420. Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties and they were consistently aware of their content.

421. Manufacturer Defendants exercised control over their deceptive messages and acted in concert⁷⁵ with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain because they funded, directed, edited, and distributed these false and misleading unbranded materials.

422. It is a well-known fact throughout the pharmaceutical industry that drug companies have been admonished for making functional claims in FDA-reviewed branded materials where there is no evidence supporting such claims.

⁷⁴ This regulation provides: “Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act.” As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

⁷⁵ As used in this complaint, the allegation that Defendants “acted in concert” with third parties and each other is intended to mean *both* that they conspired with these third parties and each other to achieve some end and that they aided and abetted these third parties and each other in the commission of acts necessary to achieve it.

423. Thus, Manufacturer Defendants were on notice that the FDA would not allow such claims in branded materials. In response, Manufacturer Defendants willfully and knowingly created and disseminated the unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through *unbranded* marketing materials.

424. The third-party publications that Manufacturer Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to such Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction. Even more deceptive and unlawful is the fact that Manufacturer Defendants knowingly cited to these sources as “independent” corroboration of their own statements.

425. Physician advisers to Manufacturer Defendants noted that the third-party documents not only had greater credibility, but broader distribution as doctors did not push back at having materials from, for example, the non-profit American Pain Foundation on display in their offices, as they might with first party, drug company pieces.

426. As part of a strategic marketing scheme, Manufacturer Defendants spread and validated their unbranded deceptive messages through the following vehicles:

- a. KOLs who could be counted upon to write favorable journal articles and deliver supportive CMEs;
- b. Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations;
- c. a body of biased and unsupported scientific literature;

- d. treatment guidelines;
- e. CMEs; and
- f. unbranded patient education materials.

3. Manufacturer Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

427. Like cigarette manufacturers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Manufacturer Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

428. Manufacturer Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages.

429. These KOLs and Front Groups have worked reciprocally with Manufacturer Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain.

430. One vehicle for their collective collaboration was Pain Care Forum (“PCF”). PCF began in 2004 as an APF project with the stated goals of offering “a setting where multiple organizations can share information” and to “promote and support taking collaborative action regarding federal pain policy issues.”

431. APF President Will Rowe described the Forum as “a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations.”

432. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American

Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendant Pharmaceutical Companies.

433. PCF, for example, developed and disseminated “consensus recommendations” for a Risk Evaluation and Mitigation Strategy (“REMS”) for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁷⁶ This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Manufacturer Defendants’ Marketing Efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were “essential” to the management of pain, and that the REMS “should acknowledge the importance of opioids in the management of pain and should not introduce new barriers.”⁷⁷

434. Manufacturer Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

435. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to Coos County prescribers and patients.

436. The collaborative actions between the Manufacturer Defendants, Front Groups and KOLs formed a critical element of the Marketing Efforts.

a. Manufacturer Defendants’ Utilization of Shill Key Opinion Leaders

⁷⁶ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

⁷⁷ Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

437. Manufacturer Defendants cultivated doctors who, upon information and belief, were selected and sponsored by such Defendants solely because they favored the aggressive treatment of chronic pain with opioids, known as key opinion leaders (“KOLs”).

438. Manufacturer Defendants’ support propelled these doctors into positions as respected industry experts.

439. In return, these doctors repaid Manufacturer Defendants by acting as Marketing Effort Shills who extolled and otherwise touted the benefits of opioids to treat chronic pain.

440. Manufacturer Defendants “pro-opioid” doctors have been at the hub of such Defendants’ promotional efforts and were used to present the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain.

441. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy.

442. KOLs have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

443. Manufacturer Defendants were able to exert control of each of the aforementioned modalities through their KOLs.

444. In return, the KOLs’ association with such Defendants provided money, prestige, recognition, research funding, and avenues to publish. All this in turn positioned the shill KOLs to exert even more influence that benefitted Manufacturer Defendants in the medical community.

445. The KOLs who initially may have advocated for more permissive opioid prescribing with honest intentions, were cultivated and promoted by Manufacturer Defendants to help broaden the chronic opioid therapy market or were dropped.

446. Manufacturer Defendants only selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.⁷⁸ These shill doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

447. Manufacturer Defendants cited and promoted favorable studies or articles by these KOLs.

448. Manufacturer Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy.

449. Indeed, Dr. Russell Portenoy, one of the more prominent KOLs sponsored by Defendants, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

450. Some KOLs have even gone on to become direct employees and executives of Manufacturer Defendants, such as Purdue's Vice President of Risk Management Dr. David Haddox and Endo's former Chief Medical Officer Dr. Bradley Galer.

451. Manufacturer Defendants artificially and with devious, unfair, and deceptive intent created substantial opportunities for KOLs to participate in research studies on topics Defendants

⁷⁸ Of course, Manufacturer Defendants marketing opioids were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

specifically chose as part of their Marketing Efforts. The predictable effect was in fact securing many favorable studies that appeared in academic literature reviewed or disseminated to their various target markets.

452. Dr. Portenoy has since made clear that drug companies would approach him with a study that was well underway and ask if he would serve as the study's author and that he regularly agreed.

453. Manufacturer Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs - typically over meals or at conferences.

454. Since 2000, Cephalon, has paid doctors more than \$4.5 million for programs relating to its opioids.

455. Each KOLs was carefully vetted by Manufacturer Defendants to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

456. Manufacturer Defendants kept close tabs on the content of the misleading materials published by these KOLs and used the information and data gleaned to further their unlawful efforts.

i. Dr. Russell Portenoy

457. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Manufacturer Defendants identified and promoted to further their Marketing Efforts.

458. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

459. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain.

460. Dr. Portenoy served on the American Pain Society (“APS”)/American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009.

461. Dr. Portenoy was a member of the board of American Pain Foundation - an advocacy organization almost entirely funded by Defendants.

462. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations.

463. Dr. Portenoy appeared on *Good Morning America* on August 30, 2010 to discuss the use of opioids long-term to treat chronic pain. This widely watched program was broadcast in Coos County and across the country. Dr. Portenoy falsely claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”

464. Dr. Portenoy has recently admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” Moreover, he recently admitted that his lectures falsely claimed that fewer than 1% of patients would become addicted to opioids.

465. According to Dr. Portenoy, the primary goal was to “destigmatize” opioids, and he and other Marketing Effort doctors promoted opioids by overstating their benefits and glossing over their risks.

466. Dr. Portenoy has conceded that “[d]ata about the effectiveness of opioids does not exist” and candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.”⁷⁹

ii. Dr. Lynn Webster

467. Another KOL essential to Manufacturer Defendants’ Marketing Efforts was Dr. Lynn Webster.

468. Dr. Webster was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake County, Utah.

469. Dr. Webster was President of the AAPM in 2013 and is a current AAPM board member.

470. The AAPM is a front group that ardently supports chronic opioid therapy.⁸⁰

471. Dr. Webster is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER.

472. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Manufacturer Defendants (including nearly \$2 million from Cephalon).

473. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010.

474. More than twenty of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

⁷⁹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.

⁸⁰ Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

475. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.

476. The claimed ability to pre-sort patients likely to become addicted was deceptively held out to be an important tool in giving doctors confidence to prescribe opioids long-term.

477. References to Dr. Webster's Opioid Risk Tool screening appear in various industry-supported guidelines and throughout Coos County.

478. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

479. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*.

480. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Coos County doctors.

481. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction."

482. Pseudoaddiction is the false, deceptive or unsupported notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain.

483. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids.

484. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

485. Endo distributed this book to doctors.

486. Years later, Dr. Webster reversed himself and acknowledged that “pseudoaddiction” obviously became too much of an excuse to give patients more medication.”⁸¹

iii. Dr. Perry Fine

487. Dr. Perry Fine is a KOL who was essential to Manufacturer Defendants’ Marketing Efforts.

488. Dr. Fine has direct connections to the Manufacturer Defendants as demonstrated by his service on Purdue’s advisory board, provision of medical legal consulting for Janssen, and participation in CME activities for Endo, along with serving in these capacities for several other drug companies.

489. With respect to Front Groups, Dr. Fine co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.⁸²

490. Dr. Fine has testified in court cases and before state and federal committees, and he has argued against legislation restricting high-dose opioid prescription for non-cancer patients.

491. Dr. Fine is the author of numerous articles that served the Marketing Efforts.

492. Dr. Fine and Dr. Portenoy co-wrote A Clinical Guide to Opioid Analgesia, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction.⁸³

493. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl

⁸¹ John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012).

⁸² Scott M. Fishman, MD, Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion, 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

⁸³ Perry G. Fine, MD and Russell K. Portenoy, MD, A Clinical Guide to Opioid Analgesia 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”⁸⁴ In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “there has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”⁸⁵

494. The article concluded that “the safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” It also concluded that the number of abuse-related events was “small.”

495. In addition, Dr. Fine effectuated the Marketing Efforts by appearing in multiple videos featuring his educational talks about opioids. In “Optimizing Opioid Therapy,” from 2011, he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.⁸⁶ He stated the “goal

⁸⁴ Perry G. Fine, *et al.*, Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

⁸⁵ *Id.*

⁸⁶ Perry A. Fine, Safe and Effective Opioid Rotation, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events over the course of years.” The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggested that opioids can be used to treat sleep apnea. He further stated that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”⁸⁷

496. Dr. Fine has conceded his failure to disclose conflicts of interest. For example, he failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s website states that the company paid him \$32,017 for consulting, promotional talks, meals and travel that year.

iv. Dr. Scott Fishman

497. Dr. Scott Fishman is another KOL physician who played a key role in the Manufacturer Defendants’ Marketing Efforts.

498. Dr. Fishman has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.”

499. In the legislative arena, he has worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to noncancer patients.

500. Dr. Fishman is the author of the seminal guides on opioid prescribing as well as other publications, which were funded by the Marketing Defendants and which downplay the risks of addiction from opioids.

⁸⁷ *Id.*

501. In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing," which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

502. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.⁸⁸

503. That guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."

504. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."⁸⁹ The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

505. Like Dr. Perry, Dr. Fishman too has conceded his failure to disclose all potential conflicts of interest. He did so in a letter in the Journal of the American Medical Association titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."⁹⁰

b. Manufacturer Defendants' Use of Front Groups to Engage in and Disseminate Deceptive Unbranded Marketing

⁸⁸ Scott M. Fishman, Responsible Opioid Prescribing: A Guide for Michigan Clinicians, 10-11 (Waterford Life Sciences 2012).

⁸⁹ Scott M. Fishman, Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication 45 (Oxford University Press 2012).

⁹⁰ Scott M. Fishman, Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, Two Leaders in Pain Treatment Have Long Ties to Drug Industry, ProPublica (Dec. 23, 2011, 2:14 PM), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry> (hereinafter "Weber, Two Leaders in Pain").

506. In addition to deploying Shill KOLs, Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous medical related organizations to promote opioids as part of their Marketing Efforts. These Front Groups depended upon Manufacturer Defendants for significant funding.

507. It is important to note that in some cases Manufacturer Defendants' funding was essential to the economic viability and credibility of these drug peddling organizations.

508. These organizations were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Manufacturer Defendants' marketing in other ways—for example, by responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing.

509. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Manufacturer Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain.

510. The Front Groups' treatment guidelines have been particularly important part of the Marketing Efforts to secure acceptance for chronic opioid therapy because they are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain.

511. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.

512. Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

513. Manufacturer Defendants funded the Front Groups to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages as part of the Marketing Efforts.

i. American Pain Foundation

514. The most prominent of Manufacturer Defendants' Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half of that funding; Purdue was next, at \$1.7 million.

515. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction.

516. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers.

517. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their “right” to pain treatment, namely opioids.

518. All of the APF and other Marketing Effort programs and materials were available in Coos County and were intended to, and did, reach Coos County residents.

519. The connection between this Front Group and the KOLs demonstrates the coordinated nature of the Manufacturer Defendants' Marketing Efforts.

520. In addition to KOLs Russell Portenoy, Perry Fine and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

521. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies out of total income of about \$3.5 million.

522. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As board member Dr. Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

523. Nevertheless, APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Defendants knew of the falsity and of APF's false and deceptive efforts.

524. APF was often called upon to provide "patient representatives" for Manufacturer Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*.

525. As laid out below, APF functioned largely as an advocate for the interests of Manufacturer Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

526. In practice, APF operated in close collaboration with opioid makers.

527. On several occasions, including informal meetings at Front Group conferences, representatives of Manufacturer Defendants suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications,

knowing that such Defendants would support projects conceived as a result of these communications.

528. APF assisted in other marketing projects for Manufacturer Defendants. One project funded by another drug company—*APF Reporter’s Guide: Covering Pain and Its Management* (2008)⁹¹—recycled text that was originally created as part of the company’s training document.

529. The same drug company made general grants, but even then, it directed how APF used them.

530. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, “I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?”

531. The close relationship between APF and the drug company was not unique, but in fact mirrors the relationships between APF and Manufacturer Defendants. APF’s clear lack of independence—in its finances, management, and mission—and its willingness to allow such Defendants to control its activities and messages, support an inference that each such Defendant that worked with APF was able to exercise editorial control over its publications.

532. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF’s credibility as an objective and neutral third party and Manufacturer Defendants stopped funding it.

⁹¹ <https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf> (last visited May 30, 2017).

533. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."⁹²

ii. The American Academy of Pain Medicine and the American Pain Society

534. The American Academy of Pain Medicine acted as another Front Group who was a key player in the Manufacturer Defendants' Marketing Efforts.

535. With the assistance, prompting, involvement, and funding of Manufacturer Defendants, AAPM issued treatment guidelines and sponsored and hosted medical education programs essential to such Defendants' deceptive marketing of chronic opioid therapy.

536. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers.

537. AAPM maintains a corporate relations council, whose members pay \$25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

538. Membership in the corporate relations council also allows Manufacturer Defendants executives and marketing staff to meet with AAPM executive committee members in small settings.

539. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

⁹² <http://www.painfoundation.org> (last visited May 17, 2017).

540. AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members.

541. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

542. The conferences sponsored by AAPM heavily emphasized sessions on opioids—thirty-seven out of roughly forty at one conference alone.

543. AAPM’s presidents have included top industry-supported KOLs Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

544. KOL Dr. Fishman stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”⁹³

545. AAPM’s staff understood that they and their industry funders were engaged in a common practice of promoting opioids.

546. Manufacturer Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

547. AAPM worked with the Front Group American Pain Society (“APS”), another professional medical society which received substantial funding from Defendants from 2009 to 2013, as part of the Marketing Efforts.

⁹³ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), *available at* <http://www.medscape.org/viewarticle/500829>.

548. AAPM and APS issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁹⁴

549. The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. KOL Dr. Portenoy was the sole consultant.

550. The consensus statement, which also formed the foundation of the FSMB Guidelines (described below), remained on AAPM's website until 2011.

551. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.⁹⁵

552. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.⁹⁶

553. Fourteen of the twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Janssen, Cephalon, Endo, and Purdue.

554. The 2009 AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.

555. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that

⁹⁴ Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf>.

⁹⁵ *Id.*

⁹⁶ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) *The Journal of Pain: Official Journal of the American Pain Society* 113-130 (2009).

drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members.

556. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Coos County during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

557. Manufacturer Defendants widely referenced and promoted the 2009 Guidelines as part of the Marketing Efforts without disclosing the acknowledged lack of evidence to support them.

iii. The Federation of State Medical Boards

558. The Front Group Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States.

559. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

560. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (“FSMB Guidelines”), which FSMB admitted was produced “in collaboration with pharmaceutical companies.”

561. The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

562. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that “inadequate understandings” of addiction can lead to “inadequate pain control.”

563. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach Coos County physicians.

564. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue.

565. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

566. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and, through the boards, to practicing doctors), and the FSMB benefitted by earning approximately \$250,000 in revenue and commissions from their sale. The FSMB website describes the book as the “leading continuing medication education (CME) activity for prescribers of opioid medications.”

567. Drug companies relied on FSMB guidelines to convey the message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

568. FSMB turned doctors’ fear of discipline on its head—doctors who used to believe that they would be disciplined if their patients became addicted to opioids were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

569. FSMB, more recently, has moderated its stance.

570. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that “pseudoaddiction” is real and that opioid addiction risk can be managed through risk screening, it no longer recommended chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

iv. American Geriatrics Society

571. Front Group the American Geriatrics Society (“AGS”), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter “2009 AGS Guidelines”).

572. The 2009 AGS Guidelines included the following recommendations: “All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation),” and “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.”⁹⁷

573. These recommendations, which continue to appear on AGS’s website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

574. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them.

575. Manufacturer Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects as part of the Marketing Efforts.

⁹⁷ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full>.

576. The 2009 Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants, including Endo and Purdue, beginning July 15, 2009.

577. Internal AGS discussions in August 2009 establish that it did not want to receive up-front funding from drug companies.

578. One reason that the AGS did not want up front funding from drug companies was because it would openly suggest drug company influence. Instead AGS accepted commercial support to disseminate the publication.

579. Manufacturer Defendants unfairly, deceptively or unlawfully conditioned financial support for the guidelines on approval of the message.

580. AGS did in fact cede significant control to Manufacturer Defendants because they were, in large part, financially dependent on them.

581. After approving the content of the guidelines, Defendants Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

582. According to one news report, AGS has received \$344,000 in funding from opioid makers since 2009.⁹⁸ Five of ten of the experts on the guidelines panel disclosed financial ties to Manufacturer Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by such Defendants, receiving grants from such Defendants, and investing in such Defendants' stock.

583. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies. *Id.*

⁹⁸ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

v. Front Groups and Guidelines That Did Not Receive Defendants' Support Reached Different Conclusions on Opioid Usage

584. Tellingly, authors of opioid guidelines that did not accept drug company funding reached very different conclusions as to the nature and extent of the science, adverse effects, risk of addiction, benefits, efficacy, health risks, and superiority which underscores the corrupt influence on treatment guidelines the Manufacturer Defendants' Marketing Efforts exerted.

585. For example, the 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it."

586. ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain."

587. ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well- selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."⁹⁹

⁹⁹ Laxmaiah Manchikanti et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

588. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits based on limited evidence,” while conceding there may be patients for whom opioid therapy is appropriate.¹⁰⁰

589. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes that their review:

revealed the lack of solid evidence-based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . . ; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . . ; lack of evidence on the utility of informed consent and opioid management plans . . . ; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.¹⁰¹

4. Manufacturer Defendants Use of Other Channels for Unbranded Materials as part of the Marketing Efforts.

a. Manufacturer Defendants’ Use of “Research” That Lacked Supporting Evidence

590. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Manufacturer Defendants’ Marketing Efforts led people to believe that they already had done so.

¹⁰⁰ American College of Occupational and Environmental Medicine’s *Guidelines for the Chronic Use of Opioids*, (2011), available at <https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf>.

¹⁰¹ Management of Opioid Therapy for Chronic Pain Working Group, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, May 2010, available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

591. As part of their Marketing Efforts Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that:

- a. understated the risks and overstated the benefits of long-term use;
- b. appeared to be the result of independent, objective research; and
- c. was thus more likely to shape the perceptions of prescribers, patients and payors.

592. This literature was, in fact, unbranded marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

593. To accomplish this, Manufacturer Defendants —sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

594. Manufacturer Defendants’ internal documents reveal plans to submit research papers and “studies” to long lists of journals, including back-up options and last resort, “fast-track” application journals, that they could use if the pending paper was rejected everywhere else.

595. As part of their Marketing Efforts Manufacturer Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs.

596. Manufacturer Defendants plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in their respective marketing departments and with marketing and public relations consultants.

597. Manufacturer Defendants often relied on “data on file” or presented posters, neither of which are subject to peer review.

598. Manufacturer Defendants also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

599. Manufacturer Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study.

600. One of the most significant publications used as support for the deceptive and unfair misrepresentation that opioids are rarely addictive is a 1980 reference in the well-respected *New England Journal of Medicine*, entitled *Addiction Rare in Patients Treated with Narcotics* by J. Porter and H. Jick, commonly known as the Porter-Jick Letter.¹⁰² That publication is cited 856 times in Google Scholar, and 86 times since 2010. It also appeared as a reference in two CME programs in 2012 sponsored by Purdue and Endo.¹⁰³

601. Manufacturer Defendants and those acting on their behalf fail to reveal that this “article” is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all).

602. The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

¹⁰² J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980).

¹⁰³ AAPM, Safe Opioid Prescribing Course, Feb. 25-26, 2012, sponsored by Purdue and Endo; “Chronic Pain Management and Opioid Use,” Oct. 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Coos County.

**ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS**

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol*. 1978; 18:180-8.

603. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations are disclosed when Manufacturer Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term.

604. Dr. Jick later complained that his letter had been distorted and misused.

605. Manufacturer Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information.

606. Manufacturer Defendants' Marketing efforts produced false and misleading studies and articles.

607. Moreover, Manufacturer Defendants' Marketing Efforts often targeted articles that contradicted such Defendants' claims or raised concerns about chronic opioid therapy. In falsely or deceptively discrediting articles or other published materials that ran against the message of the Marketing Efforts, those Defendants—often with the help of third-party consultants—targeted a

broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

608. Manufacturer Defendants' strategies included planting and promoting supportive literature and then, citing to that pro-opioid evidence in their promotional materials. All the while, Manufacturer Defendants' Marketing Efforts failed to disclose evidence that contradicted its false claims.

609. At all times relevant to this complaint, the unfair, deceptive or unlawful conduct referenced herein was entirely inconsistent with the legal obligations of Manufacturer Defendants.

610. Manufacturer Defendants' Marketing Effort strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

b. Continuing Medical Education

611. CMEs are ongoing professional education programs, provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure.

612. At all times relevant to this complaint, these programs were delivered in person, often in connection with professional organizations' conferences, online, or through written publications.

613. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice because CMEs are typically delivered by KOLs who are highly respected in their fields and are thought to reflect these physicians' medical expertise and are especially influential to doctors.

614. The countless doctors and other health care professionals who participate in accredited CMEs constituted an enormously important audience for Manufacturer Defendants' opioid re-education Marketing Efforts.

615. Again, Manufacturer Defendants each targeted their Marketing Efforts to reach general practitioners as a new target market because their practice area was necessarily broad and they lack specialized training in pain management.

616. Manufacturer Defendants targeted general practitioners because their broad area of practice rendered them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

617. Manufacturer Defendants sponsored thousands of CMEs and at each they promoted chronic opioid therapy and disseminated the deceptive unfair, deceptive or unlawful messages driven by the Marketing Efforts referenced in this complaint.

618. While often generically titled, the CMEs focused on opioids for the treatment of chronic pain to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

619. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."¹⁰⁴

¹⁰⁴ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n, Nov. 2011, available at http://eo2.commpartners.com/users/ama/downloads/120328_Opinion_E-9_0115.pdf.

620. Dozens of CMEs that were available to and attended or reviewed by Coos County doctors during the relevant time period did not live up to the AMA's standards.

621. The influence of Manufacturer Defendants' funding on the content of these CMEs is clear.

622. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article.

623. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death twenty-six times.

624. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than the other group.

625. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.¹⁰⁵

626. By sponsoring CME programs presented by Front Groups like APF, AAPM and others, Manufacturer Defendants intended to and were advantaged by messages favorable to them.

627. These organizations were otherwise dependent on Manufacturer Defendants for other projects.

¹⁰⁵ Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmOut, June 25, 2010, available at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

628. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy.

629. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids.

630. Producers of CMEs and Manufacturer Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

c. Unbranded Patient Education

631. Industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in “increasing market share . . . by bringing awareness to a particular disease that the drug treats.”¹⁰⁶

632. Manufacturer Defendants' Marketing Efforts also took into account evidence that demonstrated that physicians are willing to acquiesce to patient demands for a particular drug—even for opioids and for conditions for which they are not generally recommended.¹⁰⁷ Specifically, Manufacturer Defendants willfully and knowingly began to target their Marketing Efforts on consumers through direct-to-consumer marketing. An Actavis marketing plan overtly noted that “[d]irect-to-consumer marketing affects prescribing decisions.”

633. Manufacturer Defendants further utilized this and other related marketing data to carry out further nefarious, non-science based or driven Marketing Efforts by putting their

¹⁰⁶ Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

¹⁰⁷ Prescribers often accede to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

relationships with Front Groups to work. Specifically, such Defendants engaged in largely unbranded patient education about opioid treatment for chronic pain.

634. Manufacturer Defendants intended to and did recoup their financial investment in direct-to-consumer advertisements by capturing additional prescription profits that came about as a result of patients “asking their doctor” for opioids to treat their pain.

635. Manufacturer Defendants intended to and did recoup their financial investment in direct-to-consumer advertisements by capturing additional prescription profits that came about as a result of the review direct-to-consumer marketing materials Defendant Pharmaceutical Companies provided to distribute to patients.

5. Manufacturer Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

636. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression.

637. Manufacturer Defendants acknowledged in their labels (but not in their marketing), that the above-referenced risks occur more frequently in elderly patients.

638. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.

639. Manufacturer Defendants’ targeted marketing to the elderly and the absence of cautionary language in their promotional materials flew in the face of scientific evidence and their own labels. It created a heightened risk of serious injury to elderly patients.

640. Without an adequate scientific foundation, Manufacturer Defendants also promoted the notion that the elderly are particularly unlikely to become addicted to opioids.

641. For example, the AGS's 2009 Guidelines – which Defendants Purdue, Endo, and Janssen publicized - described the risk of addiction as “exceedingly low in older patients with no current or past history of substance abuse.”

642. Yet, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

643. Manufacturer Defendants' Marketing Efforts targeting the elderly paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

644. Manufacturer Defendants also targeted veterans in their Marketing Efforts.

645. A 2008 survey showed that prescription drug abuse among military personnel had doubled from 2002 to 2005, and then nearly tripled again over the next three years.

646. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they had in 2001.

647. As of 2012, one-third of veterans prescribed opioids remained on take-home opioids for more than 90 days. The increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment.

648. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of an accidental drug overdose—double the rate of the civilian population.

649. Opioids are particularly dangerous to veterans. According to a study published in the 2013 Journal of American Medicine:

a. veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; and

b. 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.

650. According to a VA Office of Inspector General Report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.¹⁰⁸

651. As with elderly patients, the Manufacturer Defendants' unfair, deceptive and unlawful Marketing Efforts purposefully sought to increase opioid prescribing to these vulnerable groups and omitted from their promotional materials the known, serious risks opioids pose to them.

652. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It falsely notes that opioid medications "increase a person's level of functioning" and that "long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

653. *Exit Wounds* also falsely asserts the scientifically unsupported narrative that "denying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards."

¹⁰⁸ <https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf> (last visited May 30, 2017).

654. As referenced above, the FSMB itself received support from Manufacturer Defendants during the time it created and published its guidelines.

655. *Exit Wounds* unfairly, deceptively or unlawfully minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.¹⁰⁹ *Exit Wounds* is not the unbiased narrative of a returning war veteran. It is purely unfair, deceptive unlawful marketing, sponsored by Manufacturer Defendants.

656. Purdue, Endo, and Janssen supported the unlawful marketing effort, and its insufficient disclosures, despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines “may cause respiratory depression, hypotension, and profound sedation or potentially result in coma.”

657. A similar warning is found on the labels of other Manufacturer Defendants’ opioids.

658. The deceptive nature of *Exit Wounds* is objectively established by comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011.

659. The VA’s *Taking Opioids Responsibly* describes opioids as “dangerous.”

660. The VA’s *Taking Opioids Responsibly* cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol.

661. The VA’s *Taking Opioids Responsibly* includes a list of side effects from opioids such as decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death—none of which is disclosed in *Exit Wounds*.

¹⁰⁹ FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. See FDA Notice, Guidance for Industry, “Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs,” Aug. 6, 2015.

662. Coos County has a substantial population of veterans that it supports at great cost who must cope with the consequences of the improper Marketing Efforts and the overprescribing of opioids.

D. Defendants' Marketing Messages Are Misleading and Unfair

663. Manufacturer Defendants' marketing of opioids for long-term use to treat chronic pain¹¹⁰ included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation.

664. Manufacturer Defendants' Marketing Efforts, including, but not limited to, marketing materials, omitted material information about the risks of opioids and overstated their benefits.

665. Manufacturer Defendants' Marketing Efforts inaccurately suggested that chronic opioid therapy was supported by evidence, and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

666. As follows there are seven primary misleading and unfounded representations that were advanced. Manufacturer Defendants and the third parties with which they teamed unlawfully:

- concealed the link between long-term use of opioids and addiction;
- misrepresented that opioids improve function;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them "pseudoaddiction";
- falsely claimed withdrawal is easily managed;

¹¹⁰ As stated above, Manufacturer Defendants' Marketing Efforts as referenced throughout this complaint were carried out individually as well as with and through third parties. All Marketing Efforts were unfair, deceptive, or unlawful and created a public nuisance.

- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

667. In addition to these misstatements, Purdue advanced an eighth deception - that OxyContin provides a full 12 hours of pain relief.

668. Exacerbating each of these misrepresentations and deceptions was the collective effort of Manufacturer Defendants and third parties to obfuscate and overcome the position that other alternative credible sources were “not aware of adequate and well-controlled studies of opioid use longer than 12 weeks.”¹¹¹

1. Manufacturer Defendants and their Third-Party Allies Concealed the Truth About the Risk of Addiction from Long-Term Opioid Use.

669. At all times relevant to this complaint, Manufacturer Defendants’ fraudulent representation that opioids are rarely addictive was central to the unfair, deceptive or unlawful Marketing Efforts.

670. As described above, to reach the chronic pain patient market, Manufacturer Defendants and the Front Groups and KOLs that they funded, directed, assisted, and collaborated with had to overcome the concern of prescribing physicians that opioids would addict their patients.

671. From the outset, Manufacturer Defendants knew that their Marketing Efforts would first and foremost be required to change accepted medical norms. Their targeted and methodical Marketing Efforts set out to, and did, reset norms.

¹¹¹ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

672. Prior to Manufacturer Defendants' Marketing Efforts, rank and file doctors across the country generally believed that the benefits of opioid use for common chronic pain and non-cancer related conditions were not sufficient to justify the risks associated with its use.

673. Through well-funded, comprehensive and ceaseless Marketing Efforts, Manufacturer Defendants and their KOLs and Front Groups carried out unfair, deceptive or unlawful acts, practices and omissions, including, but not limited to:

- a. making outright misrepresentations about the risk of addiction;
- b. maintaining that the risk of addiction for patients who take opioids long-term was low;
- c. omitting the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and Defendants' own labels—compelled disclosure;
- d. omitting disclosure of the risk of addiction;
- e. employing language that conveyed to prescribers that the drugs actually had lower potential for abuse and addiction;
- f. failing to disclose the serious risk of addiction at all; and
- g. using code words that conveyed to prescribers that their opioid was less prone to abuse and addiction.

674. Manufacturer Defendants and their KOLs and Front Groups falsely created the expectation of patients and prescribers that addiction rates were low, and that addiction is unlikely when opioids are prescribed for pain.

675. Each of the Manufacturer Defendants, directly or with and through third parties, falsely and knowingly claimed that the potential for addiction from its drugs was relatively small,

or non-existent and did so even though there was no scientific evidence to support those claims and the available research contradicted them.

676. A recent literature survey found that while ranges of “problematic use” of opioids ranged from <1% to 81%,¹¹² abuse averaged between 21% and 29% and addiction between 8% and 12%.¹¹³ These estimates are in line with Purdue’s own studies that found between 8% and 13% of OxyContin patients became addicted. Yet Purdue unfairly, deceptively or unlawfully chose not to rely or disclose these findings in their marketing efforts and instead cited to the Porter-Jick letter.

677. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills.

678. Opioid patients use two or more pharmacies are considered potential “red flags” for abuse or addiction.¹¹⁴

679. The FDA in fact has ordered manufacturers of long-acting opioids to “[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain,” because it found “high rates of addiction” in the medical literature.¹¹⁵

¹¹² Cited for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine*.

¹¹³ Kevin Vowels, *et al.*, *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

¹¹⁴ Len Paulozzi, M.D., “Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse,” *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244.pdf>.

¹¹⁵ September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, *available at* <http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf>; Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

680. The already significant and growing incidence of abuse, misuse, and addiction to opioids constitutes evidence that Manufacturer Defendants' statements regarding the low risk of addiction were, and are, untrue.

681. At all times relevant to this complaint, Manufacturer Defendants had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

682. In addition to denying or minimizing the risk of addiction and abuse generally, Manufacturer Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs.

683. In making these claims, Manufacturer Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting.

684. Manufacturer Defendants have never had evidence to support any of the claims.

685. FDA regulation must be based on head-to-head trials.¹¹⁶

686. The claims also were false, misleading or unlawful because they misrepresented the risks of both the particular drug and opioids as a class.

687. Rather than honestly disclose the risk of addiction, Manufacturer Defendants, and the third parties they directed and assisted and whose materials they distributed, intentionally and falsely cast those who were concerned about addiction as unfairly denying treatment to needy patients.

¹¹⁶ See *Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

688. To increase pressure on doctors to prescribe chronic opioid therapy, Manufacturer Defendants flipped the “conversation” on its head. Through such Defendants, the message became that doctors who fail to treat their patients’ chronic pains with opioids, and not doctors who cause their patients to become addicted to opioids, were failing their patients (and subject to discipline).

689. Manufacturer Defendants and their third-party allies claimed that the worries about addiction being caused by opioid pain treatment were overblown.

690. Manufacturer Defendants and their third-party allies claimed that opioid treatment for pain was under-utilized and under-prescribed.

691. Manufacturer Defendants and their third-party allies claimed that opioid pain treatment was over-regulated.

692. This mantra of under-treated pain and under-used drugs was intended to and did reinforce Manufacturer Defendants’ messages that the risks of addiction and abuse were not significant and were overblown.

693. For example, Janssen’s website, *Let’s Talk Pain*, warns in a video posted online that “strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence.” The program goes on to say: “Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States.”

2. Manufacturer Defendants and their Third-Party Allies Misrepresented that Opioids Improve Function.

694. Each of the Marketing Efforts referenced herein was created with the expectation that by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them.

695. The claims of Manufacturer Defendants unfairly, deceptively, or unlawfully encouraged doctors to continue opioid therapy because they falsely represented the true science and instilled the medically unsound belief that increasing doses or the prescribing of supplemental short-acting opioids on an as-needed basis would improve pain, functionality, or the quality of life. Rather than the breakthrough treatment falsely promoted by such Defendants, such use of opioids was entirely without scientific support.

696. There no evidence of improvement in long-term functioning from the use of opioids.

697. Moreover, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."¹¹⁷

698. The majority of medical studies on the use of opioids for the chronic conditions that Manufacturer Defendants promoted, such as low back pain, corroborate these findings and conclusions.

699. The results of independent medical studies invariably conclude that there is no improvement in chronic pain patients' conditions through long-term opioid pain treatment.

¹¹⁷ Andrea D. Furlan, *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-94 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

700. Rather scientific and medical based research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity.¹¹⁸

701. One of the Manufacturer Defendants' own internal marketing plans characterized functional improvement claims as aspirational. Another acknowledged in 2012 that significant investment in clinical data was needed to establish opioids' effect on mitigating quality of life issues, like social isolation.

702. Manufacturer Defendants do not dispute that they knew at all times relevant to the complaint that the long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade.

703. Despite the above articulated facts, the Manufacturer Defendants promoted and advanced false and deceptive marketing just the same.

704. Manufacturer Defendants also do not dispute that their Marketing Efforts' promotion of the long-term use of opioids as improving a patients' ability to function was not based on medical or scientific studies.

705. Manufacturer Defendants knowingly and intentionally omitted adverse effects, such as serious side effects, while falsely promoting the unsupported position that opioids will improve a patient's ability to function, from their publications to improve their sales and thus increase their profits.

¹¹⁸ Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared reported a lower quality of life than patients taking other medications.

to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and

reported a lower quality of life than patients taking other medications.

706. Manufacturer Defendants knowingly and intentionally used their Marketing Efforts to advance what they at all times relevant to this complaint knew to be unsupported representations.

3. Manufacturer Defendants and their Third-Party Allies Misrepresented that Addiction Risk Can Be Avoided or Managed.

707. As part of the Marketing Efforts, each Manufacturer Defendant claimed that the risk of addiction from long-term use of opioids could be avoided or managed. These claims are deceptive and without scientific support.

708. To this day, Manufacturer Defendants each continue to falsely maintain that most patients can safely take opioids long term for chronic pain without becoming addicted.

709. To explain why doctors encounter so many patients addicted to opioids, Manufacturer Defendants and their third-party allies have recently admitted that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

710. Manufacturer Defendants' assurances that doctors can identify and manage the risk of addiction were at all times relevant to this complaint driven by Marketing Efforts rather than science or good medicine.

711. There are three fundamental flaws in these Manufacturer Defendants' assurances that their screening tools were medically sound. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

712. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so.

713. A recent Evidence Report by the Agency for Healthcare Research and Quality (“AHRQ”), which “systematically review[ed] the current evidence on long-term opioid therapy for chronic pain” identified “[n]o study” that had “evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse- deterrent formulations on outcomes related to overdose, addiction, abuse or misuse.”¹¹⁹

714. Manufacturer Defendants’ Marketing Efforts were simply unsupported recommendations attempting to treat high-risk patients. High risk patients include persons who have a documented predisposition to substance abuse.

715. Manufacturer Defendants’ recommendations for patient contracts, more frequent refills, or urine drug screening are not scientifically proven to work before, during or after they were made to the prescribing doctors or consuming public.

716. Despite the widespread use of screening tools, patients with past substance use disorders receive, on average, higher doses of opioids.

4. Manufacturer Defendants and Their Third-Party Allies Falsely Advanced the Misleading Term “Pseudoaddiction.”

717. As part of the Marketing Efforts, Manufacturer Defendants and their third-party allies willfully developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are

¹¹⁹ *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

actually the product of untreated pain, doctors would prescribe opioids to more patients and continue to prescribe them, and patients would continue to use opioids despite signs that the patient was addicted.

718. The concept of “pseudoaddiction” was coined by Dr. David Haddox who went to work for Purdue.

719. The concept of “pseudoaddiction” was popularized by KOL Dr. Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue.

720. Much of the same “pseudoaddiction” language appears in other Defendants’ Marketing Efforts treatment of this issue, highlighting the contrast between “undertreated pain” and “true addiction.”

721. Patients can experience both “undertreated pain” and “true addiction.”

722. Former KOL Dr. Lynn Webster has subsequently admitted: “Pseudoaddiction” obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept.”¹²⁰

723. As part of the Marketing Efforts, each of Manufacturer Defendants in publications and/or statements falsely stated or suggested that the concept of “pseudoaddiction” is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids.

5. Defendants and Their Third-Party Allies Claimed Withdrawal Is Simply Managed.

724. Manufacturer Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty

¹²⁰ John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel, Feb. 19, 2012.

of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

725. In an effort to downplay the risk and horrific consequences of addiction, Manufacturer Defendants and their third-party allies frequently claim that, while patients become “physically” dependent on opioids, physical dependence can be addressed by gradually tapering patients’ doses to avoid the adverse effects of withdrawal.

726. Manufacturer Defendants and their third-party allies failed to disclose the extremely painful effects and very difficult road to recovery that patients can experience when they are removed from opioids. These effects make it less likely that patients will be able to stop using the drugs.

727. Withdrawal is prevalent in patients after a few weeks of opioid therapy.

728. Common symptoms of withdrawal include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

729. Manufacturer Defendants and their allies willfully and knowingly made statements or sponsored publications which falsely stated or falsely suggested that withdrawal from opioids was not a problem and that doctors should not be hesitant about prescribing opioids and the consuming public should request to use opioids.

6. Manufacturer Defendants and Their Third-Party Allies Misrepresented that Increased Doses Pose No Significant Additional Risks.

730. Each of the misrepresentations contained in Manufacturer Defendants’ Marketing Efforts was created with the intent and expectation that, by misrepresenting or failing to disclose

the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe or use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required patients to use higher doses.

731. Manufacturer Defendants and their third-party allies falsely claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that presented great risks. These claims included representations that patients would eventually reach a stable, effective dose.

732. Each of the Manufacturer Defendants' willful and false claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

733. The claims made through Manufacturer Defendants' Marketing Efforts relating to increased dosing are false.

734. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses.

735. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects.

736. The practice of continuously escalating opioid doses to match pain tolerance can lead to overdose even where opioids are taken as recommended.

737. The FDA has acknowledged that available data suggest a relationship between increased dosing and the risk of adverse effects.

738. It is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects.

739. The use of higher-dose opioids contributes to a cycle of continued or increased use because even when the drugs provide no pain relief and are causing harm addicts want more. This hunger without relief is a sign of addiction.

7. Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

740. Manufacturer Defendants' Marketing Efforts that promoted higher doses of opioids were flat misrepresentations created with the intent and expectation to drive up sales.

741. By omitting the known, serious risks of chronic opioid therapy, including the risk of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, Manufacturer Defendants acted with the intent to drive prescribers and patients to choose opioids for long-term use.

742. Manufacturer Defendants and their third-party allies routinely ignored other risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction):

- a. hyperalgesia which is a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"¹²¹
- b. hormonal dysfunction;
- c. decline in immune function;

¹²¹ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

- d. mental clouding, confusion, and dizziness;
- e. neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and
- f. potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).¹²²

743. Despite these serious risks, Manufacturer Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve).

744. While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Manufacturer Defendants' exaggerated descriptions of those risks were deceptive and misleading and made their omissions regarding the risks of opioids all the more effective. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

745. Manufacturer Defendants and their third-party allies promoted the false representation that over-the-counter NSAIDs were life-threatening.

746. Manufacturer Defendants and their third-party allies also falsely asserted that over-the-counter NSAIDs were responsible for 10,000-20,000 deaths annually (more than opioids).

747. The number of over-the-counter NSAIDs deaths is approximately 3,200.

¹²² Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, August 13, 2015. OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction ... death, ... hyperalgesia, hypogonadism ... mood altered ... overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

748. The description of NSAIDs promoted by Manufacturer Defendants and their third-party allies starkly contrasted with their representation of opioids - which had listed risks as nausea, constipation, and sleepiness and excluded addiction, overdose, or death.

749. Opioids are responsible for roughly four times as many fatalities annually as NSAID's.

8. Purdue Misleadingly Promoted OxyContin as Providing 12 Hours of Relief.

750. In addition to making the deceptive statements above, Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action.

751. Purdue also falsely promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was, upon information and belief, adapted from Purdue's own sales materials:¹²³

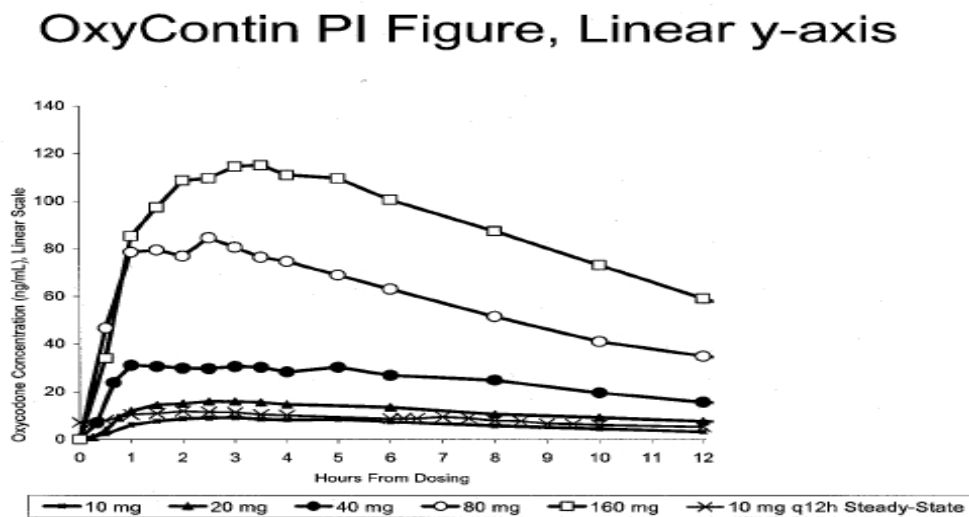


Figure 1

¹²³ Jim Edwards, "How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power," *CBSNews.com*, Sept. 28, 2011, <http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontin-addictive-power/>. The 160 mg dose is no longer marketed. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

752. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the 12 hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

753. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid—OxyContin is roughly twice as powerful as morphine—triggers a powerful psychological response.

754. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label.

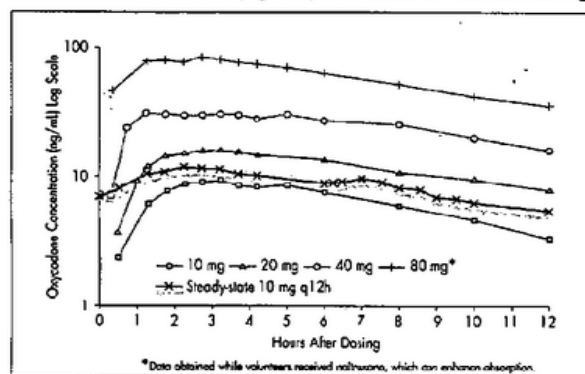
755. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full 12 hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. (The FDA found in 2008 that a “substantial number” of chronic pain patients will experience “end-of-dose failure” with OxyContin.) The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

756. Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart depicting plasma levels on a logarithmic scale. The chart minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table’s y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:

For moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time

Consistent Plasma Levels Over 12 Hours

Plasma concentrations (ng/mL) over time of various dosage strengths



• OxyContin® 80 and 160 mg Tablets FOR USE ONLY IN OPIOID-TOLERANT PATIENTS requiring minimum daily oxycodone equivalent dosages of 160 mg and 320 mg, respectively. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids

Steady state achieved within 24 to 36 hours

757. More recently, other Purdue advertisements also deceptively emphasized the false “Q12h” (meaning twice-daily) dosing protocol. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message.

758. The other advertisements that ran in the 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin with “Q12h” handwritten for emphasis.

759. The information that OxyContin did not provide pain relief for a full 12 hours was known to Purdue and Purdue’s competitors, but was not disclosed to general practitioners.

760. Purdue’s knowledge of tendency of pain specialists to prescribe OxyContin three times per day instead of two to compensate for end-of-dose failure is established through Purdue internal documents as early as 1999. It is also apparent in MEDWATCH Adverse Event reports for OxyContin.¹²⁴

761. Even Purdue’s competitor, Endo, was aware of the problem of OxyContin’s end of dose failure.

¹²⁴ MEDWATCH refers to the FDA’s voluntary adverse event reporting system.

762. In response, Endo attempted to position its Opana ER drug as offering “durable” pain relief. In so doing, Endo intended to directly contrast Opana ER with OxyContin and take market share from Purdue.

763. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin.

764. Endo ran advertisements for Opana ER referring to “real” 12-hour dosing.

765. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers in Coos County were not informed of risks relating to addiction.

766. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers in Coos County received the false or misleading message that OxyContin would be effective for treating chronic pain for the advertised duration.¹²⁵

767. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers in Coos County would compensate by increasing the dose or prescribing “rescue” opioids. So-called rescue opioids had the same effect as increasing the amount of opioids prescribed to a patient.¹²⁶

E. Each Manufacturer Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached County Prescribers.

¹²⁵ Purdue’s *Clinical Issues in Opioid Prescribing*, put out in 2005 under Purdue’s unbranded *Partners Against Pain* banner, states that “it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing.” References to “rescue” medication appear in publications Purdue sponsored such as APF’s *A Policymaker’s Guide* (2011) and the 2013 *CME Overview of Pain Management Options*.

¹²⁶ The Connecticut Attorney General’s office filed a citizens’ petition with the FDA on January 27, 2004, requesting that the OxyContin label be amended with a warning not to prescribe the drug more than twice daily as a means of compensating for end-of-dose failure. The FDA denied this request on September 11, 2008. The FDA found that the state had failed to present sufficient evidence that more frequent dosing caused adverse outcomes, but the FDA did not challenge the Connecticut finding that end-of-dose failure of OxyContin was prevalent. Indeed, the FDA found that end-of-dose failure affected a “substantial” number of chronic pain patients prescribed OxyContin.

768. Manufacturer Defendants along with their Front Groups and KOLs were able to affect a sea of change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain as a result of the Marketing Efforts.

769. Each of the Manufacturer Defendants contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which such Defendant exercised editorial control. These deceptive and misleading statements were directed to, and reached, Coos County prescribers and patients, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

770. Manufacturer Defendants willfully engaged in their deceptive marketing campaign, both nationwide and in Coos County, using the aforementioned strategies and a number more.

771. Manufacturer Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers.

772. Manufacturer Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they were and are disseminated by Defendant drug manufacturers and relate to such Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means such Defendants are liable for their content.

773. As described throughout the complaint, Coos County has located County area prescribers who received Manufacturer Defendants' misrepresentations. Each misrepresentation received by these doctors constitutes an integral piece of targeted market strategy focused on changing medical perceptions regarding the use of opioids to treat chronic pain.

774. All Manufacturer Defendants were aware of each of these misrepresentations, and each of these Defendants approved of them and oversaw their dissemination at the corporate level.

1. Actavis

775. Actavis promoted its branded opioid, Kadian, through a highly deceptive marketing campaign, carried out principally through its sales force and recruited physician speakers.

776. Actavis' internal documents establish that its campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and indeed incorporated each of the types of misleading, unfair and deceptive messages.

777. Based on the highly targeted, coordinated and uniform nature of its marketing, Actavis conveyed these misleading, unfair and deceptive messages to Coos County prescribers.

778. At all times relevant to this complaint, Actavis did so with the intent that Coos County prescribers and/or consumers would rely on its messages in choosing to use opioids to treat chronic pain.¹²⁷

a. Actavis' Deceptive Direct Marketing

779. To help devise its marketing strategy for Kadian, Actavis commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005 were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior."

780. To address these challenges, the report advocated that to overcome these challenges Actavis should include in its marketing efforts a "publication strategy based on placing in the

¹²⁷ Actavis also sold various generic opioids, including Norco, which were widely prescribed in Coos County, and benefited from Actavis's overall promotion of opioids, but were not directly marketed by sales representatives.

literature key data that influence members of the target audience” with an “emphasis . . . on ensuring that the message is believable and relevant to the needs of the target audience.” This would entail the creation of “effective copy points . . . backed by published references” and “developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile.”

781. According to the aforementioned report, such an approach would allow physicians to “reach a mental agreement” and change their “practice behavior” without having first evaluated supporting data—of which Actavis (and other Defendants) had none.

782. Actavis’ consulting firm predicted that such a manufactured body of literature “would, in turn, provide greater support for the promotional message and add credibility to the brand’s advocates” based on “either actual or *perceived* ‘scientific exchange’” in relevant medical literature. (Emphasis added).

783. To this end, Actavis planned for three manuscripts to be written during the first quarter of 2005. Of these, “[t]he neuropathic pain manuscript will provide evidence demonstrating KADIAN is as effective in patients with presumptive neuropathic pain as it is in those with other pain types”; “the elderly subanalysis . . . will provide clinicians with evidence that KADIAN is efficacious and well tolerated in appropriately selected elderly patients” and will “be targeted to readers in the geriatrics specialty”; and “[t]he QDF/BID manuscript will . . . call attention to the fact that KADIAN is the only sustained-release opioid to be labeled for [once or twice daily] use.”

784. Actavis knew exactly what each study would show—and how that study would fit into its marketing plan—before it was published. Articles matching Actavis’ descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society*.

785. To ensure that messages based on this false science reached individual physicians, Actavis deployed sales representatives, or Detailers, to visit prescribers in Coos County and across the country.

786. At the peak of Actavis's promotional efforts in 2011, the company spent \$6.7 million on detailing.

787. To track its Detailers' progress, Actavis's sales and marketing department actively monitored the prescribing behavior of physicians. It tracked the Kadian prescribing activity of individual physicians and assessed the success of its marketing efforts by tabulating how many Kadian prescriptions a prescriber wrote after he or she had been detailed. As described below, Kadian monitored numerous County physicians.

788. Actavis also planned to promote Kadian by giving presentations at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice of conferences was also influenced by the host's past support of opioids. For example, Actavis documents show that Actavis presented papers concerning Kadian at an annual meeting of AGS because AGS's guidelines "support the use of opioids."

789. Actavis targeted prescribers using both its sales force and recruited physician speakers, as described below.

i. *Actavis' Deceptive Sales Training*

790. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. Actavis sales representatives were critical in delivering its unfair, deceptive or unlawful marketing strategies and talking points to individual prescribers.

791. Actavis's strategy and pattern of deceptive marketing is established through its internal training materials. An Actavis sales education module titled "Kadian Learning System" provided its sales representatives with strictly enforced marketing messages, including, but not limited to, deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal.

792. Actavis strictly enforced its strategy of deceptive marketing and the false messages contained in its internal training materials. Sales representatives were directed and required to use them to convince prescribers, in New Hampshire and in Coos County to prescribe its opioids.

793. A sales training module, dated July 1, 2010, includes the misrepresentations documented in this complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids.

794. Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have required them to receive increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [chronic pain]."

795. Actavis also instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed

to explain to its sales representatives and, through them, to doctors, the greater risks associated with opioids at high doses.

796. The 2010 sales training module deceptively highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids thus painting the deceptive and erroneous impression that opioids are safer. The document claimed that “NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications” and “can have toxic effects on the kidney.” Accordingly, Actavis coached its sales representatives that “[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy” since “[t]hey should only be taken short term.” By contrast, the corresponding section related to opioids neglects to include a *single* side effect or risk associated with the use of opioids, including from long-term use.

797. This sales training module deceptively or falsely downplayed the main risk associated with Kadian and other opioids—addiction. It represented that “there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction” and, instead, “[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice.” Actavis, knowingly and willfully, deceptively and falsely represented that:

- a. few patients would become addicted;
- b. only patients with a prior history of abuse are at risk of opioid addiction; and
- c. doctors could effectively screen for those patients and safely prescribe to others.

798. Opioid addiction affects a significant population of patients.

799. While patients with a history of abuse may be more prone to addiction, all patients are at risk.

800. Doctors are not always able to identify, or safely prescribe to, patients at greater risk.

801. Actavis, knowingly and willfully, deceptively and falsely represented that their screening protocol would allow prescribing physicians to identify and screen out patients most likely to become addicted.

802. The sales training also noted that there were various “signs associated with substance abuse,” including, but not limited to:

- a. past history of substance or alcohol abuse;
- b family history of substance or alcohol abuse;
- c. frequent requests to change medication because of side effects;
- d. frequent requests to change medication for lack of efficacy; and
- e. a “social history of dysfunctional or high-risk behaviors including multiple arrests, multiple marriages, abusive relationships, etc.”

803. All this is deceptive and misleading because Actavis marketed the proposition that only patients with these kinds of behaviors and history become addicted to opioids.

804. The Actavis marketing efforts and sales pitches neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated.

805. The AHRQ recently issued an Evidence Report that could identify “[n]o study” that had evaluated the effectiveness of various risk mitigation strategies—including the types of patient screening implied in Actavis’s sales training—on outcomes related to overdose, addiction, abuse or misuse.

806. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of “pseudoaddiction,” which were defined as “behaviors (that mimic

addictive behaviors) exhibited by patients with inadequately treated pain.” However, the concept of “pseudoaddiction” is unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction.

807. Finally, the 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that “physical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed.” This deceptive representation overlooks the fact that the side effects associated with opiate withdrawal are severe and a serious concern for *any person* who wishes to discontinue long-term opioid therapy.

808. The Kadian Learning System module dates from July 2010.

809. Actavis sales representatives were passing deceptive messages on to prescribers even before then.

810. A July 2010 “Dear Doctor” letter issued by the FDA indicated that “between June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian].” Certain risks that were misrepresented included the risk of “misuse, abuse, and diversion of opioids” and, specifically, the risk that “opioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.” The FDA also took issue with an advertisement for misrepresenting Kadian’s ability to help patients “live with less pain and get adequate rest with less medication,” when the supporting study did not represent “substantial evidence or substantial clinical experience.”

811. Actavis’s documents also indicate that the company continued to deceptively market its drugs after 2010.

812. A September 2012 Kadian Marketing Update, and the “HCP Detail” aid contained therein, deceptively or falsely noted that Kadian’s “steady state plasma levels” ensured that Kadian “produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations” than other opioids.

813. Actavis also commissioned at least one survey of prescribers to ensure Kadian sales representatives were promoting the “steady-state” message. This survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by Actavis’s messaging.

814. A number of Kadian prescribers stated that they prescribed Kadian because it was “without the addictive potential” and wouldn’t “be posing high risk for addiction.”

815. As a result, Actavis’s marketing documents promoted that a “perception” among doctors that Kadian had “low abuse potential.”

816. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits.

817. The AAPM/APS Guidelines deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

ii. *Actavis’ Deceptive Speaking Training*

818. Actavis also increasingly relied on speakers—physicians whom Actavis recruited to market opioids to their peers—to convey similar marketing messages.

819. Actavis set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up “power lunch teleconferences” connecting speakers to up to 500 participating sites nationwide.

820. Actavis sales representatives, who were required to make a certain number of sales visits each day and week, saw the definition of sales call expanded to accommodate these changes; such calls now included physicians’ “breakfast & lunch meetings with Kadian advocate/speaker.”

821. The marketing materials and a training program for Actavis speakers included training on many of the same messages found in the Kadian Learning System, as described below.

822. The deceptive or false messages in Actavis’s speakers’ training are concerning for two reasons: (a) the doctors who participated in the training were, themselves, prescribing doctors, and the training was meant to increase their prescriptions of Kadian; and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

823. Consistent with the marketing materials and training for sales representatives, Actavis’s speakers’ training falsely minimized the risk of addiction posed by long-term opioid use. Actavis claimed, without scientific foundation, that “opioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction.” The training also deceptively touted the effectiveness of “Risk Tools,” such as the Opioid Risk Tool, in determining the “risk for developing aberrant behaviors” in patients being considered for chronic opioid therapy. In recommending the use of these screening tools, the Actavis speakers’ training willfully chose not to disclose the fact that none of the screening tools had been scientifically validated.

824. The Actavis speakers’ marketing materials and training also made reference to “pseudoaddiction” as a “condition characterized by behaviors, such as drug hoarding, that

outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain.” Actavis then purported to assist doctors in identifying those behaviors that *actually* indicated a risk of addiction from those that did not.

825. Behaviors Actavis identified as “more suggestive of addiction” included “prescription forgery,” “injecting oral formulations,” and “multiple dose escalations or other nonadherence with therapy despite warnings.”

826. Behaviors Actavis identified as “less suggestive of addiction” were “aggressive complaining about the need for more drugs,” “requesting specific drugs,” “[d]rug hoarding during periods of reduced symptoms,” and “unapproved use of the drug to treat another symptom.”

827. By portraying the risks in this manner, the Actavis speakers’ marketing materials and training presentation deceptively gave doctors a false sense of security regarding:

- a. the types of patients who can become addicted to opioids; and
- b. the types of behaviors patients who can become addicted to opioids exhibit.

828. The Actavis speakers’ marketing materials downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs.

829. For example, Actavis asserted that “Acetaminophen toxicity is a major health concern.” The slide further warned that “Acetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 US Subjects with acute liver failure between 1998-2003,” and was titled “Opioids can be a safer option than other analgesics.” However, in presenting the risks associated with opioids, the speakers’ training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines.

As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

830. The speakers' training also misrepresented the risks associated with increased doses of opioids. For example, speakers were instructed to "[s]tart low and titrate until patient reports adequate analgesia" and to "[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose." However, the marketing materials and speakers' training neglected to warn speakers (and speakers bureau attendees) that patients on high doses of opioids are more likely to suffer adverse events.

b. Actavis's Deceptive Statements to Coos County Prescribers and Patients

831. The misleading messages and training materials Actavis provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This deception by Actavis was national in scope and included Coos County.

832. Actavis's nationwide messages reached Coos County prescribers in a number of ways, including, but not limited to, the fact they were:

- a. carried into Coos County by Actavis's sales representatives during detailing visits;
- b. made available to County patients and prescribers through websites and ads, including ads in prominent medical journals; and
- c. delivered to County prescribers by Actavis's paid speakers, who were required by Actavis policy and by FDA regulations to stay true to Actavis's nationwide messaging.

833. Once trained, Actavis's sales representatives and speakers were directed to, and did, visit potential prescribers in Coos County to deliver their deceptive messages.

834. These Coos County contacts are evidenced by Actavis's substantial effort in tracking the habits of individual Coos physicians prescribing Kadian, and also by direct evidence of Actavis detailing Coos County prescribers.

835. Actavis tracked, in substantial detail, the prescribing behavior of Coos County area physicians.

2. Cephalon

836. At the heart of Cephalon's deceptive promotional efforts was a concerted and sustained effort to expand the market for its branded opioids, Actiq and Fentora, far beyond their FDA-approved use in opioid-tolerant cancer patients.

837. Trading on the rapid-onset formulation of Actiq and Fentora, Cephalon touted its opioids as the answer to "breakthrough pain".

838. Breakthrough pain is a term Cephalon's own KOL allies planted in the medical literature regardless of whether it related to cancer pain or not.

839. Cephalon promoted this deceptive or false message through its sales force, paid physician speakers, advertisements, and CMEs.

840. Cephalon promoted this deceptive or false message even after the FDA issued the company warnings and rejected an expanded drug indication.

841. While it promoted Actiq and Fentora off-label, Cephalon also purveyed many of the other deceptive messages described above. Cephalon did so directly through detailing visits and indirectly through speaker programs and the publications and CMEs of its third-party partners.

842. Cephalon deceptive or false messages included misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids.

843. Through targeted, highly coordinated and uniform marketing that saturated New Hampshire markets, Cephalon conveyed these and other deceptive messages to Coos County prescribers.

844. The materials that Cephalon generated in collaboration with third-parties were distributed or made available in Coos County. Cephalon distributed these deceptive or false messages, and facilitated their distribution, in Coos County with the intent that Coos County prescribers and/or consumers would rely on them in choosing to use its opioids to treat chronic pain.

a. Cephalon's Deceptive Direct Marketing

845. Like the other Manufacturer Defendants, Cephalon directly engaged in misleading and deceptive marketing of its opioids through its sales force and branded advertisements. These messages were centrally formulated and intended to, and did, reach prescribers nationwide, including those practicing in Coos County area.

846. Cephalon also spent the money necessary to aggressively promote its opioid drugs, setting aside \$20 million to market Fentora in 2009 alone.

i. Cephalon's Fraudulent Off-Label Marketing of Actiq and Fentora

847. Chief among Cephalon's direct marketing efforts was its campaign to deceptively promote its opioids for off-label uses.

848. Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain despite the fact that neither of its two opioid drugs Actiq or Fentora is approved for this purpose.

849. Actiq or Fentora both have indications that are clear and very narrowly defined and their use is limited their use to a particular form of cancer pain.

850. Despite these restrictions, and to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed.

851. This resulted in prescriptions written and paid and directly and proximately caused patients to be injured and die.

852. Cephalon's efforts to expand the market for its drugs beyond cancer pain extended to Coos County prescribers.

a) Cephalon Launched Its Fraudulent Marketing Scheme for Actiq

853. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate."¹²⁸

854. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications.

855. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain.

856. Actiq is a rapid-onset drug that takes effect within 10-15 minutes but lasts only a short time. Actiq is also an extremely strong drug, considered to be at least 80 times more powerful than morphine.

857. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients.

858. Actiq is not safe in any dose for patients who are not opioid tolerant.

¹²⁸ See John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J., Nov. 3, 2006.

859. Opioid tolerant refers to patients who have taken specific doses of opioids for a week or longer and whose systems have acclimated to the drugs.

860. In 1998, the FDA approved Actiq “**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”¹²⁹ (Emphasis in FDA document).

861. Because of Actiq’s dangers, wider, off-label uses—as the FDA label makes clear—are not permitted:

This product **must not** be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, ACTIQ is contraindicated in the management of acute or postoperative pain.¹³⁰

862. Actiq and Fentora are thus intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.

863. Unlike other drugs, of which off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off-label use for opioid naïve patients is barred by the FDA, as their labels make clear.

864. Notwithstanding the drug’s extreme potency and related dangers, and the FDA’s explicit limitations, Cephalon willfully and knowingly, unfairly and deceptively aggressively promoted Actiq for chronic non-cancer pain—an unapproved, off-label use.

¹²⁹ FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

¹³⁰ Actiq Drug Label, July 2011. The 1998 version does not substantively differ: “Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contra-indicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients.” (Emphasis in original).

865. Cephalon also willfully and knowingly, unfairly and deceptively marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer and for which it was not approved, appropriate, or safe.

866. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population.

867. By 2005, Actiq sales reached \$412 million, making it Cephalon's second-highest selling drug.

868. As a result of Cephalon's deceptive and unlawful marketing, sales exceeded \$500 million by 2006.

b) October 1, 2006 – Cephalon Fraudulently Marketed Actiq's Successor Drug, Fentora

869. Prior to Actiq losing its patent protection in September 2006, Cephalon took aggressive action to replace the revenue stream it would lose once generic competitors came to market.

870. Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application ("NDA") to the FDA for approval.

871. Like Actiq, Fentora is an extremely powerful and rapid-onset opioid.

872. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth.

873. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

874. Fentora’s unusually strong and detailed black box warning label—the most serious medication warning required by the FDA—makes clear that, among other things:

Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose.

Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.¹³¹

875. When Cephalon launched Fentora on October 1, 2006, it immediately implemented the unfair and deceptive marketing plan it had developed for Actiq for Fentora sales and promotions.

876. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably prescribe off-label.

877. Cephalon’s marketing of Actiq “primed the market” for Fentora.

878. Cephalon had trained numerous KOLs to lead deceptive promotional programs for Fentora, typically including off-label uses for the drug.

879. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally—not breakthrough cancer pain in particular—from Actiq.

880. Cephalon also developed a plan in 2007 to target elderly chronic pain patients via a multi-city tour with stops at AARP events, YMCAs, and senior living facilities.

881. On February 12, 2007, only four months after the launch, Cephalon CEO Frank Baldino told investors:

¹³¹ Fentora Drug Label, Feb. 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021947s008lbl.pdf.

[W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.¹³²

882. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. Roche described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses.

883. Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, identified two "major opportunities"—treating breakthrough cancer pain and:

The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . .

. . . .

We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . [opioids are] widely used in the treatment of. . . non-cancer patients

. . . .

Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.

We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.

¹³² See *Cephalon Q4 2006 Earnings Call Transcript*, Seeking Alpha (Feb. 12, 2007, 8:48 PM EST) at 5, <http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript>.

In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.¹³³

c) September 2007 – Reports of Death and Serious Side Effects Led the FDA to Issue a Public Health Warning for Fentora

884. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other “serious adverse events” connected with the use of Fentora, indicating that “these deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product substitution.”¹³⁴ The warning did not mention Cephalon’s deliberate role in the “improper patient selection” nor did the deaths and other adverse events that Cephalon had knowledge of alter their marketing efforts and misleading or false representations.

885. Two weeks after Cephalon’s September 10, 2007 sent letter to doctors warning of deaths and other “serious adverse events” connected with the use of Fentora, the FDA issued its own Public Health Advisory. The FDA again advised that Fentora should be prescribed only for approved conditions and that dose guidelines should be carefully followed.

886. The September 2007 FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label uses.

¹³³ See *Cephalon Q1 2007 Earnings Call Transcript*, Seeking Alpha (May 1, 2007, 8:48 PM EST) at 23, <http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?page=1>.

¹³⁴ Letter from Jeffrey M. Dayno, M.D., Vice President, Medical Services, Cephalon, Inc. to Healthcare Providers (Sept. 10, 2007), <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM154439.pdf>.

887. The September 2007 FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance.

888. The September 2007 FDA Advisory also reiterated that, because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.¹³⁵

889. Notwithstanding increased regulatory scrutiny, Cephalon's off-label marketing of Fentora continued.

890. Cephalon's 2008 internal audit of its Sales & Marketing Compliance Programs concluded that marketing and tactical documents, as written, may be construed to promote off-label uses. The same report acknowledged that Cephalon lacked a process to confirm that speakers' program participants were following Cephalon's written, formal policies prohibiting off-label promotion, and that "non-compliant [Cephalon Speaker Programs] may be taking place." Moreover, the report acknowledged that Cephalon's "call universe" may include "inappropriate prescribers"—prescribers who had nothing to do with cancer pain.

d) May 6, 2008 – The FDA Rejected Cephalon's Request for Expanded Approval of Fentora

891. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. Cephalon admitted that

¹³⁵ FDA Public Health Advisory, *Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm>.

Fentora already had been heavily prescribed for non-cancer pain but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.¹³⁶

892. Cephalon's Fentora application also conceded that "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

893. In response to Cephalon's application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.¹³⁷

894. By a vote of 17-3, the relevant Advisory Committee—a panel of outside experts—voted against recommending approval of Cephalon's NDA for Fentora, citing the potential harm from broader use.

895. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of Fentora's already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program.

896. In December 2008, the FDA followed that request with a formal request directing Cephalon to submit a Risk Evaluation and Mitigation Strategy for Fentora.

- e) March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") Warned Cephalon about Its Misleading Advertising of Fentora

¹³⁶ See *Fentora CII: Advisory Committee Briefing Document*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), <http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf>.

¹³⁷ See Yoo Jung Chang & Lauren Lee, *Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), <http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDAcorepresentations.ppt#289,1> (last visited May 17, 2017).

897. Undeterred by the rejection of its NDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade of Actiq for the treatment of non-cancer breakthrough pain.

898. Cephalon also continued to deceptively and unlawfully promote Fentora for use by all cancer patients suffering breakthrough cancer pain - not only those who were opioid tolerant.

899. On March 26, 2009, DDMAC issued a Warning Letter to Cephalon, formally advising Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug.¹³⁸

900. Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said “[I]earn about treating breakthrough pain in patients with cancer,”¹³⁹ was improper because it “misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy . . . when this is not the case.”

901. DDMAC emphasized that Fentora’s label was limited to cancer patients with breakthrough pain “*who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.*” (Emphasis in original). DDMAC explained that the advertisement was “especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids.” (Emphasis in original).

¹³⁸ Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (Mar. 26, 2009), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166238.pdf>.

¹³⁹ Screen shots of the sponsored link are available here: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166240.pdf>.

902. DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original).

f) Cephalon Continues to Knowingly, Deceptively, and Illegally Promote Fentora for Off-Label Uses

903. Cephalon's own market research studies confirm that its Fentora promotions were not focused on physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. The central goal of these studies was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists.

904. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists.

905. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists.

906. One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.

907. Cephalon was well aware that physicians were prescribing Fentora for off-label uses.

908. Cephalon was also aware that its detailing had an impact on prescription rates.

909. In 2011, Cephalon wrote and copyrighted an article titled “2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)” that was published in *Pain Medicine News*.¹⁴⁰ The article promoted Cephalon’s drugs for off-label uses by stating that the “judicious use of opioids can facilitate effective and safe management of chronic pain” and noted that Fentora “has been shown to be effective in treatment of [break through pain] associated with multiple causes of pain,” not just cancer.¹⁴¹

ii. *Cephalon’s Misrepresentation of the Risks Associated with the Use of Opioids for the Long-Term Treatment of Chronic Pain*

910. Cephalon’s conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension of Cephalon’s willful and knowing, deceptive or unlawful marketing plan and promotion of opioids for chronic pain and they reaped great financial benefits.

911. There is no scientific evidence corroborating a link between chronic opioid therapy and increased functionality.

912. Cephalon at all times relevant to this complaint knew that even the suggestion of a link between chronic opioid therapy and increased functionality is false.

913. Along with deploying its sales representatives, Cephalon used its speakers’ bureaus to help reach prescribers.

¹⁴⁰ <http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-remis> (last visited June 14, 2018).

¹⁴¹ *Id.*

914. At all times relevant to this complaint, Cephalon viewed each treating physician as a vehicle to generate prescriptions –whether written by that physician directly or caused indirectly by his or her influence over other physicians.

915. Having determined that speakers were an effective way to reach prescribers, Cephalon set to work ensuring that its speakers would disseminate its misleading or false messages.

916. Cephalon did not disclose to speakers that, even when its tools were applied, prescribing doctors are unable to control the risk of opioid addiction.

917. As with the other Manufacturer Defendants, Cephalon deployed the made-up concept of “pseudoaddiction” to encourage prescribers to address addictive behavior in the worst way possible—with more opioids.

918. Working with FSMB, Cephalon also trained its speakers to turn doctors’ fear of discipline on its head.

919. Doctors who previously believed that they would be disciplined if their patients became addicted to opioids, were instructed instead that they would be punished if they failed to prescribe opioids to their patients with pain.

920. Through its marketing, promotion and messaging, Cephalon willfully and knowingly, deceptively and unlawfully acted to normalize the prescribing of opioids for chronic pain.

921. In its marketing, promotion and messaging, Cephalon willfully and knowingly, deceptively and unlawfully failed to acknowledge the serious risks of long-term opioid use and that it is inappropriate as a front-line treatment for pain.

922. Finally, Cephalon also willfully and knowingly developed a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which deceptively minimized the risks of addiction from the long-term use of opioids.

923. Specifically, *Opioid Medications and REMS: A Patient's Guide* claimed that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids,” which is dangerously false.

924. Cephalon distributed the guidebook broadly, and it was available to, and intended to, and did, reach, prescribers and patients in Coos County.

925. The misleading messages and materials Cephalon provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives.

926. Cephalon's deceptive marketing plan was national in scope and included Coos County. Cephalon's nationwide messages reached Coos County prescribers in a number of ways, including, but not limited to:

- a. being delivered by Cephalon's sales representatives in detailing visits and made available to County patients and prescribers through websites and ads, including ads in prominent medical journals; and
- b. being delivered to County prescribers by Cephalon's paid speakers, who were required by Cephalon policy to stay true to the company's nationwide messaging.

b. Cephalon's Deceptive Third-Party Statements

927. Like the other Manufacturer Defendants, Cephalon also relied on third parties to disseminate its messages through deceptive publications and presentations.

928. By funding, developing and reviewing the content, and distributing and facilitating the distribution of these messages, Cephalon exercised editorial control over them. Cephalon, in some instances, used its sales force to directly distribute certain publications by these Front Groups and KOLs, rendering those publications “labeling” within the meaning of § 21 C.F.R. § 1.3(a) and making Cephalon responsible for their contents. Cephalon also deployed its KOLs as speakers for talks and CMEs to selected groups of prescribers.

929. Cephalon’s relationships with several such Front Groups and KOLs—and the misleading and deceptive publications and presentations those relationships generated—are described below.

i. *FSMB – Responsible Opioid Prescribing*

930. In 2007, Cephalon sponsored and distributed through its sales representatives FSMB’s *Responsible Opioid Prescribing*, which was drafted by KOL Dr. Fishman. Dr. Fishman was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman’s work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he now admits distorted the risks and benefits of chronic opioid therapy to meet the demands of his drug company sponsors.

931. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman’s work and contained a number of deceptive and false statements. This publication claimed that, because pain had a negative impact on a patient’s ability to function, relieving pain—alone—would “reverse that effect and improve function.” However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

932. *Responsible Opioid Prescribing* also misrepresented the likelihood of addiction by mischaracterizing drug-seeking behavior as “pseudoaddiction.” It explained that “requesting drugs by name,” engaging in “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding were all signs of “pseudoaddiction” and likely the effects of undertreated pain, rather than true addiction. There is no scientific evidence to support the concept of “pseudoaddiction,” and any suggestion that addictive behavior masquerades as “pseudoaddiction” is false.

933. Cephalon spent \$150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide. These were available to, and intended to, and did reach prescribers and pharmacists in Coos County.

ii. *APF – Treatment Options: A Guide for People Living with Pain*

934. Cephalon also exercised considerable control over the Front Group APF, which published and disseminated many of the most egregious falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, are described in detail below.

935. Documents indicate that Cephalon provided APF with substantial assistance in publishing deceptive information regarding the risks associated with the use of opioids for chronic pain. An April 3, 2008 Fentora Assessment Strategy Tactics Team Meeting presentation outlines Cephalon’s strategy to prepare for a meeting at which the FDA Advisory Committee would consider expanding the indication of Fentora to include chronic, non-cancer pain. Cephalon prepared by “reaching out to third-party organizations, KOLs, and patients to provide context and, where appropriate, encourage related activity.” First among the Front Groups listed was APF.

936. Cephalon was among the drug companies that worked with APF to “educate” the Institute of Medicine of the National Academies (“IOM”) on issues related to chronic opioid therapy. APF President Will Rowe circulated a document to Cephalon and other drug company personnel that contained key message points and suggested that they “consider using this document in your communications with the members of the IOM Committee.” According to Rowe, recipients should “consider this a working document which you can add to or subtract from.” Rowe also advised that, if recipients “have an ally on that Committee,” they should “consider sharing this document with that person.”

937. Cephalon personnel responded enthusiastically, with Cephalon’s Associate Director for Alliance Development stating her belief that “the document does a good job of bringing together many important ideas.” Cephalon reviewed and directed changes to this document, with the Cephalon Associate Director thanking Rowe “for incorporating the points we had raised.” The close collaboration between Cephalon and APF on this project demonstrates their agreement to work collaboratively to promote the use of opioids as an appropriate treatment for chronic pain.

938. Cephalon’s influence over APF’s activities was so pervasive that APF’s President, Will Rowe, even reached out to Defendants—including Cephalon—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine.

939. Starting in 2007, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain*.¹⁴² It is rife with misrepresentations regarding the risks, benefits, and superiority of opioids.

¹⁴² <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>.

940. For example, *Treatment Options* falsely asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids “give [pain patients] a quality of life [they] deserve.”

941. There is no scientific evidence corroborating that statement, and such statements are, in fact, false. Available data demonstrate that patients on chronic opioid therapy are actually *less likely* to participate in life activities like work.

942. *Treatment Options* also falsely claims that addiction is rare and is evident from patients’ conduct in self-escalating their doses, seeking opioids from multiple doctors, or stealing the drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be avoided through the use of screening tools, like “opioid agreements,” which can “ensure [that patients] take the opioid as prescribed.”

943. Nowhere does *Treatment Options* explain to patients and prescribers that neither “opioid agreements” nor any other screening tools have been scientifically validated to decrease the risks of addiction, and the publication’s assurances to the contrary are false and deceptive.

944. *Treatment Options* also deceptively or falsely promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAID overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have “no ceiling dose,” which is beneficial since some patients “need” larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids.

945. Additionally, *Treatment Options* warns that the risks associated with NSAID use increase if NSAIDs are “taken for more than a period of months,” but deceptively omits any similar warning about the risks associated with the long-term use of opioids. This presentation paints a misleading picture of the risks and benefits of opioid compared with alternate treatments.

946. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. It is currently available online and was intended to, and did, reach Coos County prescribers and pharmacists.

iii. *Key Opinion Leaders and Misleading Science*

947. Cephalon also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated by seemingly neutral scientific support.

948. Employing unscrupulous tactics, Cephalon caused the term “breakthrough pain”—a term it seeded in the medical literature—to be used in articles published by practitioners and clinicians it supported.

949. With funding from Cephalon, for example, Dr. Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of Cephalon’s Fentora. The article was published in the nationally circulated *Journal of Pain* in 2006 and helped drive a surge in Fentora prescriptions.

950. The concept of “breakthrough pain” ultimately formed the sole basis for the central theme of promotional messages Cephalon cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which begin to work very quickly but last only briefly.

951. Neither Actiq and Fentora had a natural place in the treatment of chronic pain before Cephalon’s deceptive and unlawful marketing campaign changed medical practice.

952. A recent literature survey of articles describing non-cancer breakthrough pain calls into question the validity of the concept, suggesting it is not a distinct pain condition but a

hypothesis to justify greater dosing of opioids. Cephalon conjured the science of breakthrough pain to sell its drugs.

953. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006.¹⁴³ These spikes coincide with FDA's approval of Actiq and Fentora.

iv. *Misleading Continuing Medical Education*

954. Cephalon willfully and knowingly developed sophisticated, deceptive and unlawful plans for the deployment of its KOLs, broken down by sub-type and specialty, to reach targeted groups of prescribers through CMEs.

955. Cephalon used the CME programs it sponsored to deceptively portray the risks related to the use of opioids to treat chronic non-cancer pain and promote the off-label use of Actiq and Fentora.

956. In 2007 and 2008, Cephalon sponsored three CMEs that each positioned Actiq and Fentora as the only "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs used only the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME knew it referred only to Actiq or Fentora.

957. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered online by Medscape, LLC from

¹⁴³ Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut, Georgetown U. Med. Ctr. (June 25, 2010), available at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

September 28, 2007, through December 15, 2008, was prepared by KOLs Dr. Webster and M. Beth Dove. It recommends prescribing a “short-acting opioid” (e.g., morphine, hydromorphone, oxycodone) “when pain can be anticipated,” or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (i.e., Actiq) or fentanyl effervescent buccal tablet (i.e., Fentora): “Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well.”

958. *Optimizing Opioid Treatment for Breakthrough Pain* not only deceptively or unlawfully promoted Cephalon’s drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME misrepresented that Actiq and Fentora would help patients regain functionality by advising that they improve patients’ quality of life and allow for more activities when taken in conjunction with long-acting opioids. The CME also deceptively or unlawfully minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids.

959. Around the same time, Dr. Webster was receiving nearly \$2 million in funding from Cephalon.

960. *Optimizing Opioid Treatment for Breakthrough Pain* was available online and was intended to reach County prescribers.

961. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online between March 31,

2008, and March 31, 2009, by Medscape, LLC. The direct product of Cephalon's funding was a purportedly educational document that echoed Cephalon's marketing messages.

962. The CME deceptively or unlawfully omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid Treatment* CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach County prescribers.

963. Lastly, Key Opinion Leader Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D.

964. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.¹⁴⁴ It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speakers bureau.

965. Dr. Fine also received funding from Cephalon for consulting services.

966. *Opioid-Based Management of Persistent and Breakthrough Pain* was available to and was intended to reach Coos County prescribers.

¹⁴⁴ <https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain> (last visited June 14, 2018).

967. Cephalon's had knowledge of the content of these CMEs in advance of their participation.

968. Cephalon's control over the content of these CMEs is apparent based on its advance knowledge of their content.

969. A December 2005 Cephalon launch plan set forth key "supporting messages" to position Fentora for its product launch. Among them was the proposition that "15-minute onset of action addresses the unpredictable urgency of [breakthrough pain]." Years later, the same marketing messages reappeared in the Cephalon-sponsored CMEs described above. Echoing the Cephalon launch plan, Optimizing Opioid Treatment for Breakthrough Pain stated that "[t]he unpredictability of [breakthrough pain] will strongly influence the choice of treatment" and that Fentora "delivers an onset of analgesia that is similar to Actiq at ≤ 15 minutes." Similarly, Opioid-Based Management of Persistent and Breakthrough Pain defined "breakthrough pain" as "unpredictable," over a table describing both cancer and non-cancer "breakthrough pain."

970. Cephalon tracked the effectiveness of its deceptively or unlawfully marketing through third parties, demonstrating that Cephalon not only willfully planned for third-party marketing, but also depended upon, their activities as a key element of its marketing strategy. These programs were available to prescribers in Coos County and, based on the uniform and nationwide character of Cephalon's marketing, featured the same deceptive messages described above.

c. Cephalon's Deceptive Third-Party Statements to County Prescribers and Patients

971. Cephalon used various measures to disseminate its deceptive statements regarding the risks of off-label use of Actiq and Fentora and the risks, benefits, and superiority of opioids to Coos County patients and prescribers.

972. Cephalon's speakers regularly held talks for Coos County prescribers. These talks followed the same deceptive talking points covered in Cephalon's speakers' training.

973. Cephalon also targeted Coos County prescribers through the use of its sales force.

974. Given that Cephalon's own studies demonstrated that the overwhelming majority of oncologists diagnose and treat breakthrough cancer pain themselves, Cephalon knew the only purpose of representatives meeting with these prescribers was to promote off-label use. Based on the uniform and nationwide character of Cephalon's marketing, Cephalon's deceptive messages would have been disseminated to Coos County prescribers by Cephalon's sales representatives during these events.

975. Sales representatives, and the misrepresentations on which they were trained, drove significant Actiq and Fentora sales.

3. Endo

976. Endo willfully and knowingly, deceptively or unlawfully promoted its opioids through the full array of marketing channels.

977. The company deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. deceptively or unlawfully claims about the purportedly lower abuse potential of Opana ER featured prominently in this campaign.

978. Endo also made many other deceptively or unlawfully statements and omissions. These included deceptively or unlawfully messages about functional improvement, addiction risk, "pseudoaddiction," addiction screening tools, and the safety of alternatives to opioids.

979. At the same time, Endo also relied on third-party partners to deceptively or unlawfully promote the safety, efficacy, and superiority of opioids generally, through a

combination of CMEs, websites, patient education pamphlets, and other publications. These deceptive or unlawful materials echoed the misrepresentations described above, and also made deceptive or false statements about withdrawal symptoms and the safety of opioids at higher doses.

980. Through targeted, highly coordinated and uniform marketing that saturated New Hampshire markets, Endo conveyed these deceptive messages to Coos County prescribers.

981. The materials that Endo generated in collaboration with third-parties also were distributed or made available in Coos County. Endo distributed these messages, or facilitated their distribution, in Coos County with the intent that Coos County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Endo's Deceptive Direct Marketing

982. Like the other Manufacturer Defendants, Endo used deceptive or unlawful direct marketing to increase the sales of its dangerous opioids. As set forth below, Endo conveyed these deceptive or false messages in training of its sales force and recruited speakers, who in turn conveyed them to physicians; in a misleading journal supplement; and in unbranded advertising.

i. Endo's Sales Force and Deceptive Sales Training

983. Endo's promotion of Opana ER relied heavily on in-person marketing, including to Coos County prescribers.

984. Endo had an aggressive detailing program. In the first quarter of 2010 alone, sales representatives made nearly 72,000 visits to prescribers nationwide to detail Opana ER.

985. Between 2007 and 2013, Endo spent between \$3 million and \$10 million each quarter to promote opioids through its sales force.

986. Endo's sales representatives, like those of the other Manufacturer Defendants, targeted physicians to deliver deceptively or unlawfully sales messages that were developed

centrally and deployed uniformly across the country, including Coos County. These sales representatives were critical in transmitting Endo's deceptive or unlawful marketing strategies and misleading or false talking points to individual prescribers.

987. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August, 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" more than 45% by the end of that year.

988. Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that Endo's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

989. Endo deceptively or unlawfully trained its sales force to make a number of misrepresentations to physicians nationwide, including to physicians in Coos County. Endo's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that Endo opioids had a lower potential for abuse because they were "designed to be crush resistant," despite the fact that "clinical significance of INTAC Technology or its impact on abuse/misuse ha[d] not been established for Opana ER;" and that drug seeking behavior was a sign of undertreated pain rather than addiction. These claims are all false or unsupported.

990. Endo knew that its marketing reached physicians repeatedly because it tracked its exposure.

991. Internal Endo documents dated August 23, 2006 demonstrate that the following percentages of physicians would view an Endo journal insert (or paid supplement) at least three times in an eight-month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of OB/GYNs.

992. Endo was not only able to reach physicians through its marketing, but also successfully impart its marketing messages.

993. Endo found that its deceptive or unlawful promotional materials tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future.

994. For example, according to internal Endo documents, up to 10% of physicians it detailed were able to recall, without assistance, the message that Opana ER had "Minimal/less abuse/misuse" potential than other drugs.

995. The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction.

996. Although Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse", the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage. Low abuse potential was among the deceptive or unlawful messages that County prescribers received, and retained, from Endo sales representatives.

997. Endo's own internal documents acknowledged the false and misleading nature of these statements, conceding that "Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning."

998. A September 2012 Opana ER Business Plan similarly stated that Endo needed a significant investment in clinical data to support comparative effectiveness, scientific exchange, benefits and unmet need, while citing lack of “head-to-head data” as a barrier to greater share acquisition.

999. At all times relevant to this complaint, Endo knew that its deceptive or unlawful marketing was extremely effective in turning physicians into prescribers.

1000. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescribers of Opana ER in the first quarter of 2010.

1001. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for Endo’s marketing—7.4 prescriptions per month versus 2.5.

1002. The most heavily targeted prescribers wrote nearly thirty prescriptions per month. Internal Endo documents from May 2008 indicate that Endo expected that each of its sales representatives would generate 19.6 prescriptions per week by the end of 2008.

1003. As summarized by a February 2011 report on Opana ER growth trends, Endo’s “aggressive detailing is having an impact.”

1004. More broadly, Endo’s deceptive or unlawful sales trainings and marketing plans demonstrate that its sales force was trained to provide prescribers with false or misleading information regarding the risks of opioids when used to treat chronic pain.

1005. Foremost among these messages were false or misleading claims that the risks of addiction, diversion, and abuse associated with opioids—and Endo’s products in particular—were low, and lower than other opioids.

a) Endo’s Sales Force Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy

1006. By way of illustration, Endo's Opana ER INTAC Technology Extended-Release Sell Sheet Implementation Guide, which instructs Endo sales personnel how to effectively "support key messages" related to the marketing of Opana ER, states that it is an "approved message" for sales representatives to stress that Opana ER was "designed to be crush resistant," even though this internal document conceded that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER."

1007. Other Endo documents acknowledged the limitations on Opana ER's INTAC technology, conceding that while Opana ER may be resistant to pulverization, it can still be "ground" and "cut into small pieces" by those looking to abuse the drug.

1008. Endo's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to County patients and prescribers.

1009. The only reason to promote the crush resistance of Opana ER was to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. The idea that Opana ER was less addictive than other drugs was the precise message that County prescribers took from Endo's marketing.

1010. On May 10, 2013 the FDA warned Endo that there was no evidence that Opana ER's design "would provide a reduction in oral, intranasal, or intravenous abuse" and that the post-marketing data Endo had submitted to the FDA "are insufficient to support any conclusion about the overall or route-specific rates of abuse."

1011. Even though it was rebuked by the FDA, Endo continued to market Opana ER as having been *designed* to be crush resistant, knowing that this would (falsely) imply that Opana

actually *was* crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused.

1012. On June 8, 2017, in an unprecedented move, the FDA officially requested that Endo remove Opana ER from the market. The FDA cited its reasoning as “its concern that the benefits of the drug may no longer outweigh its risks.”¹⁴⁵ The FDA acknowledged that “[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequence of its abuse.”¹⁴⁶

1013. Endo’s sales trainings, and their promotional and educational materials, deceptively or unlawfully taught prescribing physicians that the risk of addiction was minimal. For example, Endo circulated an education pamphlet with the Endo logo titled “Living with Someone with Chronic Pain,” which implied, to persons providing care to chronic pain patients, that addiction was not a substantial concern by stating that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” This pamphlet was downloadable from Endo’s website and accessible to County prescribers.

1014. Endo’s sales training also misrepresented the risks of addiction associated with Endo’s products by implying that Opana’s prolonged absorption would make it less likely to lead to abuse. For example, a presentation titled “Deliver the Difference for the Opana Brand in POA II” sets out that one of the “key messages” for the Endo sales force was that Opana ER provides “[s]table, steady-state plasma levels for true 12-hour dosing that lasts.” Endo’s sales representatives used this deceptive or unlawful messaging to imply to County prescribers that

¹⁴⁵ FDA News Release “FDA requests removal of Opana ER for risks related to abuse”, *available at* <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm>.

¹⁴⁶ *Id.*

Opana ER provided “steady state” pain relief, making Opana less likely to incite euphoria in patients and less likely to lead to addiction.

1015. Endo further deceptively or unlawfully instructed its sales force to promote the misleading concept of “pseudoaddiction”. In a sales training document titled “Understanding the Primary Care MD and their use of Opioids,” Endo noted that the “biggest concerns” among primary care physicians were “prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%).” In response to these concerns, Endo instructed its sales representatives to ask whether their customers were “confusing ‘pseudo-addiction’ with ‘drug-seekers’” and how confident they were that their health care providers “know these differences (Tolerance, Dependence, Addiction, Pseudo- Addiction . . .).”

b) Endo’s Sales Force Deceptively Implied that Chronic Opioid Therapy Would Improve Patients’ Ability to Function

1016. In addition to their deceptive or unlawful messages regarding addiction, Endo’s promotional materials and sales trainings also falsely and misleadingly claimed that patients using opioids for the long- term treatment of chronic pain would experience improvements in their daily function.

1017. Endo knew at all times relevant to this complaint that long-term opioid use has not been shown to, and does not, improve patients’ function, and, in fact, is often accompanied by serious side effects that degrade function.

1018. Endo’s own internal documents acknowledged that claims about improved quality of life were unsubstantiated “off label claims.”

1019. Nevertheless, Endo deceptively or unlawfully distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front:

“Janice is a 46-year-old chef with chronic low back pain. She needs a treatment option with true 12-hour dosing.” The false or deceptive advertisement does not mention the “moderate to severe pain” qualification in Opana ER’s indication, except in the fine print. These advertisements were mailed to prescribers and distributed by Endo’s sales force in detailing visits, which would have included Endo representatives’ visits to prescribers.

1020. In a 2007 sales tool, designed and intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named “Bill,” a 40-year-old construction worker who was reported to suffer from chronic low back pain. According to the Sales Tool, Opana ER will make it more likely that Bill can return to work and support his family.

1021. Similarly, training materials for sales representatives from March 2009 ask whether it is true or false that “[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself.” The materials indicate that this is “false” because “the overall effect of treatment with opioids is very favorable in most cases.”

1022. A sales training video dated March 8, 2012 that Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that “chronic pain [. . .] reduces your functional level.” Jeffery claims that after taking Opana ER, he “can go out and do things” like attend his son’s basketball game and “[t]here’s no substitute for that.” This video was shown to Endo’s sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in Coos County.

1023. Claims of improved functionality were central to Endo’s deceptive or unlawful marketing efforts for years. A 2012 Endo Business Plan lists way to position Opana ER, and among

them is the claim that Opana ER will help patients “maintain normal functionality, sleep, and work/life/performance productivity” and have a positive “effect on social relationships.” Indeed, that business plan describes the “Opana ER Vision” as “to make the Opana franchise (Opana ER, Opana, Opana Injection) the choice that maximizes improvement in functionality and freedom from the burden of moderate-to-severe pain.”

c) Endo’s Sales Force Deceptively Presented the Risks and Benefits of Opioids to Make Them Appear Safer Than Other Analgesics

1024. Endo further misled patients and prescribers by deceptively or unlawfully downplaying the risks of opioids in comparison to other pain relievers. For example, in Coos County and elsewhere, Endo distributed a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed “a massive upper gastrointestinal bleed.” The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

1025. Endo distributed *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to 116,000 prescribers in 2007, including primary care physicians.

ii. *Endo’s Speakers Bureau Programs Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy*

1026. In addition to its sales representatives’ visits to doctors, Endo also used deceptive science and speaker programs to spread its deceptive messages.

1027. Endo leaned heavily on its designed speakers’ bureau programs.

1028. In 2008 alone, Endo spent nearly \$4 million to promote up to 1,000 speakers' programs around the country.

1029. Endo contracted with a medical communications firm to operate its speakers' bureau program, planning to hold a total of 500 "fee-for-service . . . peer-to-peer promotional programs" for Opana ER in just the second half of 2011, including dinners, lunches and breakfasts. These programs were attended by sales representatives, revealing their true purpose as marketing, rather than educational, events.

1030. Endo's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. Endo measured that return on investment in numbers of prescriptions written by physicians who attended the events. One internal Endo document concluded: "[w]e looked at the data for [the] 2011 program and the results were absolutely clear: physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that."

1031. These speakers' bureau presentations included the very same deceptive or unlawful misrepresentations Endo disseminated through its sales representatives. A 2012 speaker slide deck for Opana ER—on which Endo's recruited speakers were trained and to which they were required to adhere to in their presentations—misrepresented that the drug had low abuse potential, in addition to suggesting that as many as one-quarter of the adult population could be candidates for opioid therapy.

1032. In addition, a 2013 training module directed speakers to instruct prescribers that "OPANA ER with INTAC is the only oxymorphone designed to be crush resistant" and advised that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe OPANA ER with INTAC." This was a key point in distinguishing

Opana ER from competitor drugs. Although Endo mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that “[t]he generics are not designed to be crush resistant.” This was particularly deceptive given that Opana ER was not actually crush-resistant.

1033. In 2009, Endo wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain*. The talk included a slide titled “Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain,” which cited the AAPM/APS Guidelines—and their accompanying deceptive or unlawful misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients’ past abuse histories) while omitting their disclaimer regarding the lack of supporting evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

1034. The misleading messages and materials Endo provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, irrespective of the risks, benefits, and alternatives. This deception was instituted throughout New Hampshire and included Coos County.

1035. Endo’s nationwide messages would have reached Coos County prescribers in a number of ways, including, but not limited to, being:

- a. carried into Coos County by Endo’s sales representatives during detailing visits as well as made available to County patients and prescribers through websites and ads; and
- b. delivered to County prescribers by Endo’s paid speakers, who were required by Endo policy and by FDA regulations to stay true to Endo’s nationwide messaging.

iii. *Endo’s Misleading Journal Supplement*

1036. In 2007, Endo commissioned the writing, and paid for the publishing of a supplement available for CME credit in the Journal of Family Practice called Pain Management Dilemmas in Primary Care: Use of Opioids, and it deceptively minimized the risk of addiction by emphasizing the effectiveness of screening tools.

1037. Endo deceptively or unlawfully recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain.

1038. Endo also falsely claimed that, through the use of tools like toxicology screens, pill counts, and a “maximally structured approach,” even patients at high risk of addiction could safely receive chronic opioid therapy.

1039. Endo distributed 96,000 copies of this CME nationwide, and it was available to, and was intended to, reach County prescribers.

iv. *Endo’s Deceptive Unbranded Advertising*

1040. Endo also deceptive or unlawful used unbranded advertisements to advance its goals. By electing to focus on unbranded marketing, Endo was able to make claims about the benefits of its opioids that the FDA would never allow in its branded materials. The chart below compares an Endo unbranded statement with one of Endo’s FDA-regulated, branded statements:

Living with Someone with Chronic Pain (2009)(Unbranded)	Opana ER Advertisement (2011/2012/2013) (Branded)
Patient education material created by Endo	Endo advertisement

<p>“Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”</p>	<p>“Contains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit.”</p> <p>“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.”</p>
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b. Endo’s Deceptive Third-Party Statements

1041. Endo’s deceptive or unlawful efforts were not limited to directly making misrepresentations through its marketing materials, its speakers, and its sales force. Endo believed that support for patient advocacy and professional organizations would reinforce Endo’s position as “the pain management company.”

1042. In contemplation of, the 2006 launch of Opana ER, Endo developed a “Public Stakeholder Strategy.” Endo identified “tier one” advocates to assist in promoting the approval and acceptance of its new extended release opioid. Endo also intended to enlist the support of organizations that would be “favorable” to schedule II opioids from a sales perspective and that engaged in, or had the potential to advocate for, public policy. Endo sought to develop its relationships with these organizations through its funding.

1043. In 2008, Endo spent \$1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing (“ASPMN”).

1044. APF’s ability to influence professional societies and other third parties is demonstrated by its approach to responding to a citizens’ petition filed with the FDA by the Physicians for Responsible Opioid Prescribing (the “PROP Petition”). The PROP Petition, filed

by a group of prescribers who had become concerned with the rampant prescribing of opioids to treat chronic pain, asked the FDA to require dose and duration limitations on opioid use and to change the wording of the approved indication of various long-acting opioids to focus on the severity of the pain they are intended to treat.

1045. The PROP Petition set off a flurry of activity at Endo. It was understood that Endo would respond to the petition, but Endo personnel wondered “should we consider filing a direct response to this [citizens’ petition] or do you think we are better served by working through our professional society affiliations?” One Endo employee responded: “My sense is the societies are better placed to make a medical case than Endo.” Endo’s Director of Medical Science agreed that “a reply from an external source would be most impactful.” These communications reflected Endo’s absolute confidence that the professional societies would support its position.

i. *APF*

1046. One of the societies with which Endo worked most closely was APF. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control (“NIPC”).

1047. Endo was one of APF’s biggest financial supporters, providing more than half of the \$10 million APF received from opioid manufacturers during its lifespan.

1048. Endo spent \$1.1 million on the NIPC program in 2008 alone, funding earmarked in part, for the creation of CME materials that were intended to be used repeatedly.

1049. Endo’s influence over APF’s activities was so pervasive that APF President Will Rowe reached out to Defendants—including Endo—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of

Internal Medicine. Personnel from Defendants Purdue, Endo, Janssen, and Cephalon worked with Rowe to formulate APF's response which was ultimately published.

1050. Documents also indicate that Endo personnel were given advance notice of the materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July of 2009, APF's Director of Strategic Development wrote to Endo personnel to give them advance notice of content that APF planned to be "putting . . . up on the website but it's not up yet." The Endo employee assured the sender that she "would not forward it to anyone at all" and promised that she would "'double delete it' from her inbox." In response, APF's Director of Strategic Development replied internally with only four words: "And where's the money?"

1051. At no time was Endo's relationship with APF closer than during its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services which the Accreditation Council for Continuing Medical Education determined to be a "commercial interest" and could no longer serve as a sponsor. In response, Endo reached out to APF. An August 2009 document titled "A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control," pointed out that "[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc." According to this document, APF's sponsorship of the NIPC "offers the APF a likely opportunity to generate new revenue, as Endo has earmarked substantial funding: \$1.2 million in net revenue for 2010 to continue the NIPC." Further, sponsorship of the APF would "provide numerous synergies to disseminate patient education materials," including "handouts to attendees at all live events to encourage physicians to drive their patients to a trusted source for pain education—the APF website."

1052. A September 14, 2009 presentation to APF's board contained a materially similar discussion of NIPC sponsorship, emphasizing the financial benefit to APF from assuming the role of administering NIPC. The proposal "offer[ed] a solution to continue the development and implementation of the NIPC initiative as non-certified . . . yet independent education to physicians and healthcare professionals in the primary care setting, while providing the APF with a dependable, ongoing source of grant revenue." A number of benefits related to NIPC sponsorship were listed, but chief among them was "a likely opportunity [for APF] to generate new revenue, as Endo has earmarked substantial funding: \$1.2 million in net revenue for 2010 to continue the NIPC."

1053. Internal Endo scheduling documents indicate that "NIPC module curriculum development, web posting, and live regional interactive workshops" were Endo promotional tasks in 2010. Endo emails indicate that Endo personnel reviewed the content created by NIPC and provided feedback.

1054. Behind the scenes, Endo exercised substantial control over NIPC's work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in the distribution of NIPC and APF materials, which in effect determined which messages were actually delivered to prescribers and consumers. As described below, Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

1055. From 2007 until at least 2011, Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo's commercial interest in, and access to, NIPC's reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, Painknowledge.com. Endo not only knew how many people viewed NIPC's content, but

what their backgrounds were (e.g., primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

1056. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. Endo's 2008 to 2012 Opana Brand Tactical Plan indicates that it sought to reach 1,000 prescribers in 2008 through live NIPC events, and also to “leverage live programs via enduring materials and web posting.”

1057. Endo also planned to disseminate NIPC's work by distributing two accredited newsletters to 60,000 doctors nationwide for continuing education credit and by sponsoring a series of eighteen NIPC regional case-based interactive workshops. Endo had earmarked more than one million dollars for NIPC activities in 2008 alone.

1058. NIPC was a key piece of Endo's marketing strategy.

1059. Internal APF emails question whether it was worthwhile for APF to continue operating NIPC given that NIPC's work was producing far more financial benefits for Endo than for APF.

1060. After Endo approved a \$244,337.40 grant request to APF to fund a series of NIPC eNewsletters, APF personnel viewed it as “great news,” but cautioned that “the more I think about this whole thing, Endo's making a lot of money on this with still pretty slender margins on [APF's] end.” APF's commitment to NIPC's “educational” mission did not figure at all in APF's consideration of the value of its work, and Endo's motive and benefit were never in doubt.

a) Misleading Medical Education

1061. NIPC distributed a series of eNewsletter CMEs focused on “key topic[s] surrounding the use of opioid therapy” sponsored by Endo. These newsletters were edited by Key Opinion Leader Dr. Fine and listed several industry-backed KOLs, including Dr. Webster, as individual authors. Endo estimated that roughly 60,000 prescribers viewed each one. These CMEs were available to, and would have been accessed by, Coos County prescribers.

1062. Before-and-after surveys, summarized in the chart below, showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic	<u>Comfort level <i>prior</i> to reading the article</u>	<u>Comfort level <i>after</i> reading the article</u>
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimize Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies Into the Opioid Treatment Plan	42%	85%
Addressing Patients' Concerns Associated With Chronic Pain Treatment and Opioid Use	62%	92%
Opioid Therapy in Patients With a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an “Exit Strategy”	37%	90%

1063. Endo documents made it clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, Endo personnel knowingly and deceptively directed that, when giving Endo-sponsored talks, NIPC faculty would not appear to be “Endo Speakers.”

1064. Nevertheless, the two parties agreed that Endo and NIPC shared a common “mission to educate physicians” and working “through the APF . . . was a great way to work out . . . problems that could have been there without the APF’s participation and support.”

1065. The materials made available on and through NIPC included misrepresentations and falsities. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have “possibly less potential for abuse” in elderly patients than in younger patients, even though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient’s doses by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” NIPC webcast these CMEs from its own website, where they were available to, and were intended to reach, County prescribers.

b) Pain Knowledge

1066. Working with NIPC enabled Endo to make a number of misleading or false statements through the NIPC’s website, *Painknowledge.com*. Endo tracked visitors to *PainKnowledge.com* and used *Painknowledge.com* to broadcast notifications about additional NIPC programming that Endo helped to create.

1067. APF made a grant request to Endo to create an online opioid “tool-kit” for NIPC and to promote NIPC’s website, *Painknowledge.com*. In so doing, APF made clear that it planned to disseminate Defendants’ misleading or false messaging. The grant request expressly indicated

APF's intent to make Endo's unsupported claims relating to functionality, noting "some of these people in chronic pain may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life." Endo provided \$747,517 to fund the project.

1068. APF's adhered to the spirit and word of its conspiracy with Endo. *Painknowledge.com* advanced the scientifically unsupported claim that opioid therapy for chronic pain would lead to improvements in patients' ability to function.

1069. Among other false or misleading representations, in 2009 the *Painknowledge.com* website falsely instructed patients and prescribers that with opioids:

- a. a patient's "level of function should improve"; and
- b. a patient "may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse."

1070. *Painknowledge.com* also falsely minimized the risk of addiction by claiming that "people who take opioids as prescribed usually do not become addicted." *Painknowledge.com* did not stop there.

1071. *Painknowledge.com* also falsely portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

1072. Endo was the sole funder of *Painknowledge.com*, and it continued to provide that funding despite having actual knowledge of the website's misleading or false contents.

c) *Exit Wounds*

1073. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain.

1074. *Exit Wounds* was drafted by Derek McGinnis.”

1075. Janssen contracted with a medical publishing firm, Conrad & Associates, LLC.

1076. The content was drafted by a writer (“Medical Writer X”) hired by Conrad & Associates and funded by Janssen.

1077. These draft materials of *Exit Wounds* were reviewed, in detail, by Janssen’s medical-legal review team. Janssen medical legal review team conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

1078. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Janssen, and fully accepted that the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain.

1079. Medical Writer X knew and fully accepted the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. Medical Writer X knew of the drug company’s sponsorship of the publication, and he would go to the company’s website to learn about the drug being promoted.

1080. Medical Writer X knew and fully accepted that his clients—including Janssen—would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe, and the risk of addiction is low; (b) opioids are effective for chronic pain; and (c) opioids are under-prescribed because doctors are hesitant, confused, or face other barriers.¹⁴⁷

¹⁴⁷ Medical Writer X now acknowledges that the lists of adverse effects from chronic opioid use in the publications he authored, which excluded respiratory depression, overdose, and death and minimized addiction, were, “ridiculous” and “prime examples” of leaving out facts that the pharmaceutical company sponsors and KOLs knew at the time were true. His writings repeatedly described the risk of addiction as low. Medical Writer X stated that he understood that the goal was to promote opioids and, as a result, discussing addiction would be “counterproductive.”

1081. Medical Writer X was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science.

1082. Medical Writer X's work was reviewed and approved by drug company representatives.

1083. Medical Writer X felt compelled to draft pieces that he now admits he distorted the risks and benefits of chronic opioid therapy to meet the demands of his drug company sponsors.

1084. *Exit Wounds* is a textbook example of Medical Writer X's authorship on drug companies' behalf. The book misrepresented the functional benefits of opioids by stating that opioid medications "*increase* your level of functioning" (emphasis in original).

1085. *Exit Wounds* also misrepresented that the risk of addiction associated with the use of opioids to treat chronic pain was low.

1086. *Exit Wounds* falsely claims that "long experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

1087. Finally, *Exit Wounds* deceptively or unlawfully misrepresented the safety profile of using opioids to treat chronic pain by omitting key risks associated with their use. Specifically, it omitted warnings of the risk of interactions between opioids and benzodiazepines—a warning sufficiently important to be included on Endo's FDA-required labels.

1088. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids—a particular risk for veterans.

1089. As referenced above, Endo exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain.

1090. In addition, Medical Writer X's work was being reviewed and approved by drug company representatives, motivating him to draft pro-opioid propaganda masquerading as science. Combined, these factors gave Endo considerable influence over the work of Medical Writer X and over APF. Further, by paying to distribute *Exit Wounds*, Endo has established that endorsed and approved its contents.

ii. *Other Front Groups: FSMB, AAPM, and AGS*

1091. In addition to its involvement with APF, Endo worked closely with other third-party Front Groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, Endo used its sales force to directly distribute the publications of these Front Groups and KOLs thus making those publications "labeling" within the meaning of 21 C.F.R. § 1.3(a).

1092. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Dr. Fishman."

1093. Endo spent \$246,620 to help FSMB distribute *Responsible Opioid Prescribing*. Endo approved this book for distribution by its sales force. Based on the targeted, uniform and nationwide character of Endo's marketing campaign, and the fact that Endo purchased these copies specifically to distribute them, these copies were distributed to physicians nationwide, including physicians in Coos County.

1094. In December 2009, Endo also contracted with AGS to create a CME to promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a \$44,850 donation. These scientifically unsupported guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse".

as the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)” when in reality, opioid therapy was only an appropriate treatment for a subset of those patients, as recognized by Endo’s FDA-mandated labels.

1095. AGS’s grant request to Endo made explicit reference to the CME that Endo was funding. Thus, Endo knew full well what content it was paying to distribute and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether or not to invest in it.

1096. After having sponsored the AGS CME, Endo’s internal documents indicate that Endo’s pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

1097. Endo also worked with AAPM, which it viewed internally as “Industry Friendly,” with Endo advisors and speakers among its active members.

1098. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

1099. A talk written by Endo in 2009 and approved by Endo’s Medical Affairs Review Committee,¹⁴⁸ titled *The Role of Opana ER in the Management of Chronic Pain*, includes a slide titled *Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain*. That slide

¹⁴⁸ Although they were given slightly different names by each Manufacturer Defendants, each Defendant employed a committee that could review and approve materials for distribution. These committees included representatives from all relevant departments within Defendants’ organizations, including the legal, compliance, medical affairs, and marketing departments. The task of these review committees was to scrutinize the marketing materials Defendants planned to distribute and to ensure that those materials were scientifically accurate and legally sound. Tellingly, these committees were called to review only materials that created a potential compliance issue for the company, an implicit recognition by Defendants that they ultimately would be responsible for the content under review.

cites the AAPM/APS Guidelines, which contain a number of false or misstatements and omits their disclaimer regarding the lack of supporting scientific evidence. This talk dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

1100. Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

iii. *Key Opinion Leaders and Misleading Science*

1101. Endo also sought to unlawfully or deceptively promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

1102. Endo's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin).

1103. Endo sought to unlawfully or deceptively achieve that goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and subsequently successfully had articles on this topic published.¹⁴⁹

1104. In the years that followed, Endo sponsored articles authored by Endo consultants and Endo employees, which argued that the metabolic pathways utilized by Opana ER, compared with other opioids, were less likely to result in drug interactions in elderly low back and osteoarthritis pain patients.

¹⁴⁹ These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

1105. In 2010, Endo directed its publication manager to reach out to a list of consultants conducting an ongoing Endo-funded study, to assess their willingness to respond to an article¹⁵⁰ that Endo believed emphasized the risk of death from opioids, “without [] fair balance.”¹⁵¹

1106. Endo’s reliance on scientifically unsupported, flawed, or biased research is also established in its 2012 marketing materials and strategic plans.

1107. A 2012 Opana ER slide deck for Endo’s speakers’ bureaus—on which these recruited physician speakers were trained and to which they were required to strictly adhere misrepresented that the drug had low abuse potential and suggested that as many as one-quarter of the adult population could be candidates for opioid therapy.

1108. The FDA requires such speaker slide decks to reflect a “fair balance” of information on benefits and risks. Endo’s unlawful or deceptive slides reflect one-sided and deeply biased information. The presentation’s twenty-eight literature citations were largely to “data on file” with the company, posters, and research funded by, or otherwise connected to, Endo. Endo’s speakers relayed the information in these slides to audiences that were unaware of the false or skewed science on which the information was based.

1109. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnote referenced in the document, which it unlawfully or deceptively cited to indicate “no gap” in scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it deceptively did so out of context. For example, it cited a 2008 review article on opioid efficacy

¹⁵⁰ Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 New Engl. J. Med. 1981 (2010), finding that opioid overdose deaths and opioid prescriptions both increased by roughly ten-fold from 1990 to 2007.

¹⁵¹ Endo did manage to get a letter written by three of those researchers, which was not published.

for several claims, including that “treatment of chronic pain reduces pain and improves functionality,” but it ignored the article’s overall focus on the lack of consistent effectiveness of opioids in reducing pain and improving functional status.¹⁵²

1110. Notwithstanding Endo’s willful and knowing reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness.

1111. Endo also cited a lack of “head-to-head data” as a barrier to greater share acquisition, and the “lack of differentiation data” as a challenge to addressing the “#1 Key Issue” of product differentiation. This acknowledged lack of support did not stop Endo from unlawfully or deceptively directing its sales representatives to falsely tell prescribers that its drugs were less likely to be abused or be addictive than other opioids.

1112. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that “[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems,” implying that patients who are taking opioids for pain are not at risk of addiction.

1113. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked “[i]f I take the opioid now, will it work later when I really need it?” and responded that “[t]he dose can be increased... [y]ou won’t ‘run out’ of pain relief.”

¹⁵² Andrea M. Trescot et al., *Opioids in the management of non-cancer pain: an Update of American Society of the Interventional Pain Physicians*, Pain Physician 2008 Opioids Special Issue, 11:S5-S62.

1114. Dr. Portenoy received research support, consulting fees, and honoraria from Endo for editing *Understanding Your Pain* and other projects.

1115. *Understanding Your Pain* was available on Endo's website during the time period of this Complaint and was intended to, and did, reach County prescribers.

1116. Endo similarly distributed a book written by Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

1117. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "increase the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs." The slide indicates that the book would be particularly effective "for [the] PCP audience" and instructed "sales representatives [to] deliver [the book] to participating health care professionals." The slide, shown below, demonstrates Endo's express incorporation of this book by a KOL into its marketing strategy:

Opioid Abuse and Managing Pain Handbook	
Objective:	◆ Provide value added educational offering
Description:	◆ Handbook provides educational resource, in particular for PCP audience ◆ Introduction of program via direct mail ◆ Sales representatives delivery to participating healthcare professionals
Timing:	◆ 1Q-3Q
Investment:	◆ \$350,000

Callout: Increase the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs

Handbook Cover: *Avoiding Opioid Abuse While Managing Pain* by Lynn R. Webster, MD, and Beth Davis. A Guide for Practitioners.

Footer: Confidential - For Internal Use Only
DRAFT - Pending Management Approval
35
Accelerating Our Growth

1118. Endo documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal Endo documents establish that the book had been approved for distribution by Endo's sales force, and that Endo had fewer than 8,000 copies on

hand in March of 2013. Based on the targeted, nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to, and did, reach Coos County prescribers.

c. Endo's Deceptive Statements to County Prescribers and Patients

1119. Endo also unlawfully or deceptively directed the dissemination of the misstatements described above to Coos County patients and prescribers, including through its sales force, speakers' bureaus, CMEs, and the *Painknowledge.com* website.

1120. Consistent with their training, Endo's sales representatives unlawfully or deceptively delivered all of these deceptive messages to Coos County prescribers.

1121. Endo also unlawfully or deceptively directed misleading marketing to Coos County prescribers and patients through the APF/NIPC materials it sponsored, reviewed, and approved. For example, Endo hired a New York-based KOL to deliver a CME titled *Managing Persistent Pain in the Older Patient* on April 27, 2010. As described above, this CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients' ability to function. An email invitation to the event and other NIPC programs was sent to "all healthcare professionals" in APF's database.

1122. The significant response to *Painknowledge.com* also indicates that those websites were viewed by Coos County prescribers, who were then exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids.

1123. As of September 14, 2010, *Painknowledge.com* had 10,426 registrants, 86,881 visits, 60,010 visitors, and 364,241 page views.

1124. Upon information and belief, based on the site's nationwide availability, among the site's visitors were Coos County patients and prescribers who were then exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids.

1125. At all times relevant to this complaint, Endo knew that the harms from its deceptive marketing would be felt in Coos County.

1126. Endo saw workers' compensation programs as a lucrative opportunity, and it promoted the use of opioids for chronic pain arising from work-related injuries, like chronic lower back pain. Endo developed plans to "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees."

1127. In 2007, Endo planned to reach 5,000 workers' compensation carriers to ensure that Opana ER would be covered under disability insurance plans.

1128. Endo knew or should have known that claims for its opioids would be paid for by Coos County's workers' compensation program.

4. Janssen

1129. Janssen unlawfully or deceptively promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program.

1130. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of Janssen's marketing campaign.

1131. Janssen also willfully and knowingly conveyed other misrepresentations including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

1132. Janssen unlawfully or deceptively supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain.

1133. Janssen's materials and marketing efforts made false or deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. Janssen's materials and marketing efforts also falsely claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

1134. Through targeted, highly coordinated and uniform marketing that saturated New Hampshire markets, Janssen conveyed these deceptive messages to County prescribers.

1135. The materials and marketing efforts that Janssen generated in collaboration with third-parties also were distributed or made available in Coos County.

1136. Janssen distributed these messages, or facilitated their distribution, in Coos County with the intent that Coos County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Janssen's Deceptive Direct Marketing

1137. Janssen joined the other Defendants in unlawfully or deceptively disseminating and otherwise effectively using materials and marketing efforts that propagated deceptive brand. The unlawfully or deceptively marketing falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain.

1138. Like the other Defendants, Janssen sales representatives visited targeted physicians to deliver unlawful or deceptive sales messages that were developed centrally and deployed identically across the country. These sales representatives were essential to Janssen's transmission of misinformation and its marketing strategies and talking points to individual prescribers.

1139. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than \$90 million on detailing.

1140. Janssen's intent to increase sales through deceptive marketing is established on the face of its marketing plans. For example, although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, its Nucynta Business Plans indicated that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug.

1141. At all times relevant to this complaint, Janssen knew there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low.

1142. At all times relevant to this complaint, Janssen knew that there were severe symptoms associated with opioid withdrawal, including, severe anxiety, nausea, vomiting, hallucinations, and delirium; yet Janssen touted the ease with which patients could come off opioids.

i. *Janssen's Deceptive Sales Training*

1143. Janssen's sales force was compensated based on the number of Nucynta prescriptions written in each sales representative's territory.

1144. Janssen encouraged these sales representatives to maximize sales of Nucynta and meet their sales targets by relying on the false and misleading statements described above.

1145. For example, Janssen's sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like Nucynta because of their fear of addicting patients, but this reluctance is unfounded because "the risks . . . are [actually] much smaller than commonly believed."

1146. Janssen also encouraged its sales force to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A Janssen sales training PowerPoint titled "Selling Nucynta ER and Nucynta" falsely indicates that the "low incidence of opioid withdrawal symptoms" is a "core message" for its sales force. The message was touted at Janssen's Pain District Hub Meetings, in which Janssen periodically gathered its sales force personnel to discuss sales strategy.

1147. Janssen's "core message" of a lack of withdrawal symptoms runs throughout Janssen's sales training materials is totally untrue and utterly lacks any scientific support.

1148. Janssen's "Licensed to Sell" Facilitator's Guide instructed those conducting Janssen sales trainings to evaluate trainees, in part, on whether they represented that "withdrawal symptoms after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively" and whether they were able to "accurately convey" this "core message." Janssen further falsely claimed in 2008 that "low incidence of opioid withdrawal symptoms" was an advantage of the tapentado molecule.

1149. Similarly, a Nucynta Clinical Studies Facilitator's Guide instructs individuals training Janssen's sales representatives to ask trainees to describe a "key point"—that "83% of

patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy”—“as though he/she is discussing it with a physician.”

1150. This misrepresentation regarding withdrawal was one of the key messages Janssen instructed employees to spread in the “Retail ST 101 Training” delivered to Nucynta sales representatives.

1151. Training modules between 2009 and 2011 falsely instruct training attendees that “most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms” and “[n]o patients experienced moderately severe or severe withdrawal symptoms.”

1152. During the very time Janssen was deceptively or unlawfully instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Nucynta to treat chronic pain, it knew or should have known, that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction.

1153. Janssen also knew or should have known that its studies on withdrawal were flawed and created a misleading impression of the rate of withdrawal symptoms and, as a result, the risk of addiction.

1154. The false or misleading messages and materials Janssen provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, irrespective of the risks, benefits, and alternatives.

1155. Janssen’s deception was national in scope and included Coos County Janssen’s nationwide messages reached Coos County prescribers in a number of ways, including but not limited to:

- a. its sales force in detailing visits, as well as through websites and ads; and

- b. delivery to County prescribers by Janssen's paid speakers, who were required by Janssen policy and by FDA regulations to stay true to Janssen's nationwide messaging.

- ii. *Janssen's Deceptive Speakers Bureau Programs*

1156. Janssen did also disseminated its false or misleading messages regarding chronic opioid therapy through its sales force.

1157. It also hired speakers to promote its opioids and trained them to make the very same false statements or deceptive misrepresentations made by its sales representatives.

1158. Janssen's speakers were required to present from slide decks that contained false statements or deceptive misrepresentations and misleading information about the risks, benefits, and superiority of opioids outlined above. For example, a March 2011 speaker's presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain.

1159. *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* deceptively or unlawfully completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and other known, serious risks associated with chronic opioid therapy.

1160. *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* presentation also falsely or deceptively minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms."

1161. An August 2011 speaker presentation *New Perspectives in the Management of Moderate to Severe Chronic Pain* contained the same false and misleading discussion of the risks associated with chronic opioid therapy.

1162. *New Perspectives in the Management of Moderate to Severe Chronic Pain* It similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER “abruptly without initiating alternative opioid therapy” reported no withdrawal symptoms whatsoever. The same deceptive claims regarding risks of adverse events and withdrawal appeared in a July 2012 speaker’s presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models*.

1163. These speakers’ presentations were part of Janssen’s nationwide marketing efforts. Upon information and belief, a number of these events were available to and were intended to, and did, reach Coos County prescribers.

iii. *Janssen’s Deceptive Unbranded Advertising*

1164. Janssen had actual knowledge that its branded advertisements and speakers’ programs would face regulatory scrutiny that would not apply to its unbranded materials, so Janssen deceptively or unlawfully engaged in direct and indirect unbranded marketing.

1165. One such unbranded project was Janssen’s deceitful or unlawful creation and maintenance of *Prescriberresponsibly.com* (last updated July 2, 2015), a website aimed at prescribers and patients that claims that concerns about opioid addiction are “overstated.” A disclaimer at the bottom of the website states that the “site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content.” This website was available to and intended to, and did, reach Coos County prescribers and patients.

b. Janssen’s Deceptive Third-Party Statements

1166. Janssen’s efforts were not limited to directly making misrepresentations through its sales force, speakers’ bureau, and website. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, Janssen deceptively or unlawfully obscured its involvement in certain marketing activities by “collaborating with key patient advocacy organizations” to release misleading information about opioids.

i. *AAPM and AGS – Finding Relief: Pain Management for Older Adults*

1167. Janssen worked deceitfully or unlawfully or with AAPM and AGS to create a false or misleading patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). In doing so, they contracted with Medical Writer X to create the publication.

1168. *Finding Relief* is rife with false or deceptive content.

1169. *Finding Relief* represents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The representations are not based in science and are driven by marketing.

1170. The guide falsely represents as a “fact” that proposition that “opioids may make it *easier* for people to live normally” (emphasis in the original).

1171. The functional claims contained in *Finding Relief* are textbook examples of Defendants’ use of third parties to disseminate messages the FDA would not allow Janssen to say themselves. *Compare, e.g.:*

Branded Advertisement That Triggers an FDA Warning Letter (2008)¹⁵³

Improvement in Daily Activities Includes:

- | |
|--|
| <ul style="list-style-type: none"> • Walking on a flat surface • Standing or sitting |
|--|

¹⁵³ This advertisement drew an FDA Warning Letter dated March 24, 2008. Though the advertisement was by drug company King, it is used here to demonstrate the types of claims that the FDA regarded as unsupported.

- Climbing stairs
- Getting in and out of bed or bath
- Ability to perform domestic duties

with:

**Seemingly Independent Publication: “Finding Relief: Pain Management for Older Adults”
(Final Authority, Janssen 2009):**

Your recovery will be measured by how well you reach functional goals such as

- Sleeping without waking from pain
- Walking more, or with less pain
- Climbing stairs with less pain
- Returning to work
- Enjoying recreational activities
- Having sex
- Sleeping in your own bed

1172. *Finding Relief* also deceptively trivialized the risks of addiction by falsely describing as a “myth” that opioids are addictive and asserting as fact that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”

1173. *Finding Relief* also falsely represented opioids were safe at high doses. They accomplished this by listing dose limitations as “disadvantages” of other pain medicines and omitting any discussion of risks from increased doses of opioids.

1174. *Finding Relief* also falsely claimed that it is a “myth” that “opioid doses have to be bigger over time.”

1175. Finally, *Finding Relief* also falsely or deceptively overstated the risks associated with alternative forms of treatment. It juxtaposed the advantages and disadvantages of NSAIDs on one page, with the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses

or for a long time,” “adverse reactions in people with asthma,” and “increase[d] . . . risk of heart attack and stroke.”

1176. The only adverse effects of opioids listed by *Finding Relief* are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation. This is false, deceptive and lacks any basis in science. The *Finding Relief* guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

1177. Janssen was not a passive sponsor of *Finding Relief*. Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. A “Copy Review Approval Form” dated October 22, 2008 indicates that key personnel from Janssen’s Advertising & Promotion, Legal, Health Care Compliance, Medical Affairs, Medical Communications, and Regulatory Departments reviewed and approved *Finding Relief*.

1178. All six Janssen personnel approving the publication checked the box on the approval form indicating that *Finding Relief* was “Approved With Changes.”

1179. The publication was modified at the behest of Janssen personnel. Janssen then paid to have its sales force distribute 50,000 copies of *Finding Relief* throughout the nation. Thus, *Finding Relief* is considered labeling for Janssen’s opioids within the meaning of 21 C.F.R. § 1.3(a).

1180. AAPM purchased and distributed copies of *Finding Relief* to all of its members, including those who reside in Coos County.

ii. *AGS – Misleading Medical Education*

1181. Janssen also worked with AGS on another project—AGS’s CME promoting the 2009 guidelines for the Pharmacological Management of Persistent Pain in Older Persons.

1182. These Pharmacological Management of Persistent Pain in Older Persons guidelines falsely claimed that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse” although the study supporting this assertion did not analyze addiction rates by age.

1183. The Pharmacological Management of Persistent Pain in Older Persons also falsely stated, that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation).”

1184. Janssen had control over AGS’s Finding Relief, and Janssen exercised control over this project as well.

iii. *APF*

1185. Janssen also unlawfully or deceptively worked with APF to carry out its false or misleading marketing campaign.

1186. Documents obtained from one of Janssen’s public relations firms, Ketchum, indicate that Janssen and the firm enlisted APF as part of an effort to “draft media materials and execute [a] launch plan” for Janssen’s drugs at an upcoming meeting of the AAPM. Janssen also deceptively or unlawfully drew on APF publications to corroborate claims in its own marketing materials and its sales training.

1187. Janssen personnel participated in a March 2011 call with APF’s “Corporate Roundtable,” in which they worked with APF and drug company personnel to develop strategies to promote the scientifically unsupported chronic opioid therapy. APF personnel spoke with Janssen employees who “shar[ed] expertise from within their company for [a] public awareness campaign.”




1188. Their joint work on the “Corporate Roundtable” demonstrates the close collaboration between Janssen and APF in promoting opioids for the treatment of chronic pain. APF President Will Rowe also reached out to Defendants—including Janssen— rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Additional examples of APF’s collaboration with Janssen are laid out below:

a) Let’s Talk Pain

1189. Most prominent among these efforts was the *Let’s Talk Pain* website. Janssen sponsored *Let’s Talk Pain* in 2009, acting in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing. Janssen financed and orchestrated the participation of these groups in the website.

1190. Janssen exercised substantial control over the content of the *Let’s Talk Pain* website. Janssen’s internal communications always referred to *Let’s Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER. Janssen regarded *Let’s Talk Pain* and another website—*Prescriberresponsibly.com*— as integral parts of Nucynta’s launch:

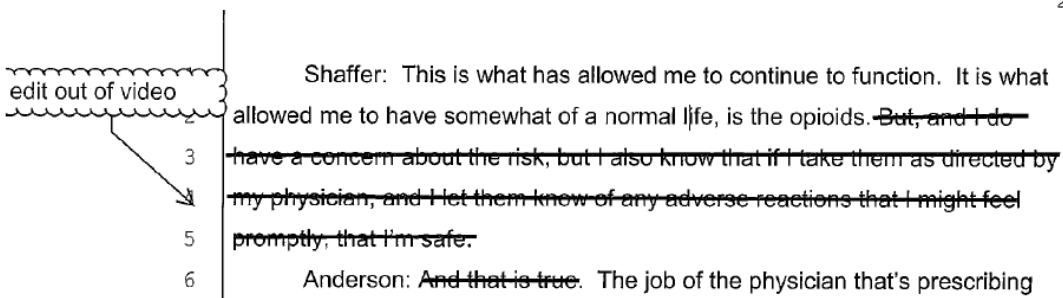
PR/Communication Plan for NUCYNTA ER

	UNMET NEEDS	PAIN LEADERSHIP	DIFFERENTIATE	STRONG EFFICACY AND FAVOURABLE GI TOLERABILITY PROFILE
BRANDED	<ul style="list-style-type: none"> Promote clinical evidence for NUCYNTA ER with data-driven press releases (Q2-Q4) PDUFA Date with various media using KOLs (Top-tier media, Social media) (Q3) <div style="display: flex; justify-content: space-around; align-items: center;">      </div> <ul style="list-style-type: none"> Art exhibit featuring art from chronic pain patients at HCP-focused PAINWeek (Sep) Other (Blogger briefing in Q3, Testimonial of chronic pain patients, Online media briefing on pain management) 			
UNBRANDED	<ul style="list-style-type: none"> Smart Moves, Smart choices Prescribe responsibly Let's talk Pain <div style="display: flex; justify-content: space-around; align-items: center;">    </div>			

1191. Janssen documents also reveal that Janssen personnel viewed APF and AAPM as “coalition members” in the fight to increase market share.

1192. To this end, Janssen and APF deceptively or unlawfully entered into a partnership to “keep pain and the importance of responsible pain management top of mind” among prescribers and patients. They agreed to work to wrongfully reach and spread false or misleading information described herein to target audiences marked by Janssen’s marketing department that included but was not limited to patients, pain management physicians, primary care physicians, and KOLs.

1193. One of the roles Janssen assumed in the process was to “[r]eview, provide counsel on, and approve materials.” Janssen did in fact review and approve material for the *Let’s Talk Pain* website, as evidenced by the following edits by a Janssen executive to the transcript of a video that was to appear on the site:



1194. The final version of the video on *Let's Talk Pain* deceptively cut and omitted the stricken language above.

1195. This review and approval authority extended to the *Let's Talk Pain* website. Emails between Janssen personnel and a consultant establish that, even though the *Let's Talk Pain* website was hosted by APF, Janssen had approval rights over its content. Moreover, emails describing Janssen's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions." Janssen used *Let's Talk Pain* as its shill.

1196. As a 2009 Janssen memo conceded, "[t]he *Let's Talk Pain Coalition* is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara **maintain editorial control of all *Let's Talk Pain* materials and publications**" (emphasis added).

1197. A 2011 Consulting Agreement between Janssen and one of APF's employees, relating to the dissemination of national survey data, demonstrates the near-total control Janssen was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including requiring APF to circulate and post Janssen's promotional content. The agreement required APF to "participate in status calls between Janssen, APF, AAPM, ASPMN, and Ketchum as requested by Janssen" and required APF to "respond to requests to schedule status calls **within 48 hours** of the request" (emphasis in original). APF also was required to "review and provide feedback to

media materials, including a press release, pitch email, a key messages document, and social media messages, **within one week** of receipt” (emphasis in original).

1198. The agreement further required APF to provide a summary of the survey results in APF’s PAIN MONITOR e-newsletter, post a link to the survey results on APF’s Facebook page, send out tweets related to the survey, serve as a spokesperson available for media interviews, “[s]hare information with any media contacts with whom APF has existing relationships to promote the announcement of the national survey findings,” identify at least two patient spokespersons to talk about the survey data, and include the survey results in “any future APF materials, as appropriate.” Tellingly, “any ideas made or conceived by [APF] in connection with or during the performance” of the agreement “shall be the property of, and belong to, [Janssen].”

1199. Janssen also wrongfully exercised control over *Let’s Talk Pain*. Janssen updated the *Let’s Talk Pain* website to describe its corporate restructuring and Janssen personnel wrongfully asserted their control over “video additions” by reviewing and deceptively or unlawfully editing the interview touting the functional benefits of opioids. Given its editorial control over the content of *Let’s Talk Pain*, Janssen, at all times, had actual knowledge of and was fully and actively involved in shaping the website’s deceptive or false content.¹⁵⁴

1200. *Let’s Talk Pain* contained a number of false representations that had no basis in science.

1201. As referenced above, *Let’s Talk Pain* falsely represented that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality. *Let’s Talk Pain* featured an interview claiming that opioids were what allowed a patient to “continue to function.”

¹⁵⁴ It bears noting that Janssen does not publicly identify its role in creating *Let’s Talk Pain*’s content. Instead, *Let’s Talk Pain* represents that “coalition members” develop the content that appears on the website and lists Janssen as the only sponsor of that coalition.

This video is still available today on YouTube.com and is accessible to Coos County prescribers and patients.

1202. In 2009, *Let's Talk Pain* also promoted “pseudoaddiction,” which it described as patient behaviors that may occur when pain is under-treated” but differs “from true addiction because such behaviors can be resolved with effective pain management” (emphasis added). *Let's Talk Pain* was available to, and was intended to, and did, reach Coos County patients and prescribers.

b) Exit Wounds

1203. Janssen also wrongfully engaged in other promotional projects with and through APF. As described above, one such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively or falsely portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by Medical Writer X. It is fully representative of his work on behalf of drug companies.

1204. Janssen gave APF substantial assistance in distributing *Exit Wounds* in Coos County and throughout the nation by providing grant money and other resources.

c. **Janssen's Deceptive Statements to Coos County Prescribers and Patients**

1205. Janssen also wrongfully directed the misstatements described above to Coos County patients and prescribers, including through CMEs, its sales force, and recruited physician speakers.

i. *Janssen's Deceptive Medical Education Programs in Coos County*

1206. Janssen sponsored CMEs and talks attended by Coos County prescribers.

ii. *Janssen's Deceptive Detailing Practices in Coos County*

1207. Experiences of specific prescribers confirm that Janssen's national marketing campaign included the misrepresentations and that the company disseminated these same misrepresentations to Coos County prescribers and consumers.

1208. Prescriber accounts reflect that Janssen detailers deceptively or falsely claimed that

- a. Nucynta was "not an opioid" because it worked on an "alternate receptor"¹⁵⁵;
- b. Janssen's drugs would be less problematic for patients because they had anti-abuse properties;
- c. Janssen's drugs would be less problematic for patients because they were "steady state";
- d. patients on Janssen's drugs were less susceptible to withdrawal; and
- e. opioids were safer than NSAIDs.

1209. Janssen detailers also deceptively or falsely overstated the benefits of opioids, including, but not limited to, making claims of improved function.

1210. Janssen detailers deceptively or falsely omitted or minimized the risk of opioid addiction.

5. Purdue

1211. Purdue's principal opioids were Oxycontin, Butrans, and Hysingla.

1212. Generally, Purdue promoted its branded opioids and its other opioids in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement.

¹⁵⁵ The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as an "opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit."

1213. Purdue promoted its branded opioids through its sales force, branded advertisements, promotional materials, and speakers, as well as a host of materials produced by its third-party partners, most prominently APF.

1214. Purdue's sales representatives, advertising and other marketing efforts falsely or misleadingly represented or implied that OxyContin provides a full 12 hours of pain relief.

1215. Purdue's in tandem with its allied Front Groups and KOLs conveyed additional false or deceptive messages including but not limited to those detailed above and relating to:

- a. the safety of opioids at high doses;
- b. the risks of alternative therapies; and
- c. the effectiveness of addiction screening tools.

1216. Through targeted, highly coordinated and uniform marketing that saturated New Hampshire markets, Purdue conveyed these deceptive messages to Coos County prescribers.

1217. The materials that Purdue generated in collaboration with third parties were distributed or made available in Coos County.

1218. In Coos County, Purdue distributed these messages or facilitated their distribution through third parties with the intent that Coos County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Purdue's Deceptive Direct Marketing

1219. Like the other Manufacturer Defendants, Purdue willingly and knowingly directly created, contributed to and disseminated false or deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of opioids to treat chronic pain. Purdue also directed that this false or inaccurate marketing was directed to prescribers and consumers through its sales force, branded advertisements and allies.

1220. Purdue deployed its sales representatives to doctors' offices, clinics, pharmacies, and hospitals to push its opioids in New Hampshire, including in Coos County.

1221. As described above in the context of its Co-Defendant detailers' activities, Purdue sales representatives visited targeted physicians to deliver sales messages. The sales messages were developed centrally and deployed by a marketing department and were identically uniformly and identically presented or delivered across the country. Purdue's sales representatives were an essential cog in Purdue's propaganda machine because they carried Purdue's marketing strategies and false or deceptive talking points to individual prescribers.¹⁵⁶

1222. During their visits, Purdue salespeople asked doctors to identify specific patients they were scheduled to see, and pushed the doctors to assure them that they would put those patients on Purdue opioids. By the time an unknowing patient arrived at the doctor's office, his or her doctor had already committed to prescribing Purdue's drugs. Purdue further enticed doctors by rewarding them with meals, gifts, and money.

1223. Purdue's use of face-to-face meetings and sales pitches was intentionally aimed at cloaking its deceptive and unscrupulous activities. When one of its sales representatives wrote down an email in a sales pitch, which was against Purdue's practice of avoiding making a record of its illegal activities, Individual Purdue Defendant Russell Gasdia, Vice President of Sales and Marketing, ordered, "Fire her now!"

1224. Co-Defendant Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines,

¹⁵⁶ But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

which as discussed above, falsely or deceptively represented that the risk of addiction is manageable for patients regardless of past abuse histories with doctors during individual sales visits.

1225. In 2006 and 2007, Purdue faced civil and criminal charges for misbranding OxyContin.

1226. After settling those charges in 2007, Purdue sharply increased its quarterly spending on its false or deceptive marketing through its sales force. Purdue spent under \$5 million in 2007 and more than \$30 million by the end of 2014.

1227. Purdue employed other deceptive tactics as part of its Marketing Effort in New Hampshire. It streamed videos to healthcare providers on its OxyContin Physicians Television Network.

1228. Purdue also falsely or deceptively marketed its drugs through branded advertisements. Among other unlawful or wrongful tactics, the branded advertisements relied on misleading statements about the efficacy and onset of OxyContin. Purdue marketed its drug as effective for 12 hours despite possessing actual knowledge that these claims were false or misleading.

1229. Purdue had actual knowledge that the pain relief of OxyContin lasted for as little as eight hours for many patients and this led to end-of-dose failure and withdrawal symptoms.

1230. Purdue had actual knowledge that end of dose failure prompted doctors to prescribe, or patients to take, higher or more frequent doses of opioids.

1231. Purdue had actual knowledge that all of these aforementioned factors increased the risk of abuse and addiction.

1232. The “Conversion and Titration Guide” was submitted to the FDA and distributed to physicians by Purdue.

1233. The “Conversion and Titration Guide” prominently referred to “Q12h OxyContin Tablets,” which meant that each tablet was intended to “offer . . . every-twelve-hour dosing.”

1234. Additional false or deceptive marketing materials directed at physicians and disseminated across the country in 2006 touted that OxyContin’s “12-hour AcroContin Delivery System” was “designed to deliver oxycodone over 12 hours,” which offered patients “life with Q12H relief.” These same marketing materials included a false or deceptive timeline graphic with little white paper pill cups at “8AM” and, further down the line, at “8PM” only. They also falsely or deceptively represented that OxyContin provided “Consistent Plasma Levels Over 12 Hours” and set forth charts demonstrating absorption measured on a logarithmic scale. This intentional marketing effort fraudulently made it appear that levels of oxycodone in the bloodstream slowly taper over a 12-hour time period.

1235. Purdue advertisements that ran in 2005 and 2006 issues of the *Journal of Pain* depicted a sample prescription for OxyContin with “Q12h” handwritten.

1236. An additional advertisement that Purdue ran in 2005 in the *Journal of Pain* touted OxyContin’s “Q12h dosing convenience” and displayed two paper dosing cups, one labeled “8 am” and one labeled “8 pm,” implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 *Clinical Journal of Pain*.

1237. Purdue willfully and intentionally continued to include prominent false or deceptive 12-hour dosing instructions in its branded advertising, such as in a 2012 Conversion and Titration Guide, which states: “Because each patient’s treatment is personal / Individualize the dose / Q12h OxyContin Tablets.”

1238. As outlined above, these statements are false or misleading because they fail to make clear that a 12-hour dose does not equate to 12 hours of pain relief. Despite having actual knowledge to the contrary, Purdue's direct marketing materials misleadingly claimed OxyContin offers 12-hour "dosing convenience."

1239. As described below, the false or deceptive statements regarding the efficacy of OxyContin were also carried into Coos County by Purdue's detailers.

1240. Purdue's direct marketing materials also falsely or deceptively represented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

1241. In 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function and that there was substantial evidence to the contrary.

1242. In addition to the unbranded materials that Purdue channeled through third parties described below, some of the greatest weapons propelling Purdue's false and deceptive marketing efforts were unbranded materials it directly funded and authored.

1243. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence—of addiction. However, Purdue had actual knowledge that OxyContin was used non-medically by injection less than 17% of the time.

1244. Despite Purdue having actual knowledge to the contrary, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as “Indications of Possible Drug Abuse”—downplaying much more prevalent signs of addiction associated with OxyContin use such as asking for early refills, making it seem as if addiction only occurs when opioids are taken illicitly.

1245. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of “pseudoaddiction” rather than addiction itself.

1246. Specifically, *Providing Relief, Preventing Abuse* noted that the concept of “pseudoaddiction” had “emerged in the literature” to describe “[drug-seeking behaviors] in patients who have pain that has not been effectively treated.” Nowhere in *Providing Relief, Preventing Abuse* did Purdue disclose the lack of scientific evidence justifying the concept of “pseudoaddiction,” or that the phrase itself had been coined by a Purdue vice president.

1247. *Providing Relief, Preventing Abuse* was available nationally and was intended to, and did, reach Coos County prescribers and consumers. As described herein, the deceptive statements in *Providing Relief, Preventing Abuse* regarding addiction were the very same messages Purdue directed at Coos County prescribers through its sales force.

1248. Purdue also disseminated false or deceptive representations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

1249. Consistent with Purdue’s efforts to portray opioid treatment as “essential” for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an “inadequate understanding” that leads to “inadequate pain control.”

1250. *In the Face of Pain* complains, under the heading of “Protecting Access,” that, through at least mid-2013, policy governing the prescribing of opioids was “at odds with” best medical practices by “unduly restricting the amounts that can be prescribed and dispensed”; “restricting access to patients with pain who also have a history of substance abuse”; and “requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe.”

1251. *In the Face of Pain* criticized policies that limited access to opioids as being “at odds with best medical practices” and encouraged patients to be “persistent” in finding doctors who will treat their pain. Purdue unlawfully or deceptively intended this imply that patients should keep looking until they find a doctor willing to prescribe opioids.

1252. *In the Face of Pain* was wholly untrue rhetoric that aims to portray doctors who do not prescribe opioids as uncaring, converting their desire to relieve patients’ suffering into a mandate to prescribe opioids.

1253. *In the Face of Pain* was a product of Manufacturer Defendants’ Marketing Efforts and not science.

1254. *In the Face of Pain* was available nationally and was intended to, and did, reach Coos County prescribers.

1255. Purdue also unlawfully or deceptively used its unbranded website *Partners Against Pain* to promote the same false messages regarding risk of addiction that were delivered by its sales representatives.

1256. Purdue posted *Clinical Issues in Opioid Prescribing*, a pamphlet that was copyrighted in 2005, on its *Partners Against Pain*. Purdue also distributed hard-copy versions of this pamphlet.

1257. *Clinical Issues in Opioid Prescribing* claimed that “illicit drug use and deception” were not indicia of addiction, but rather indications that a patient’s pain was undertreated. The publication falsely or deceptively indicated that “pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.” In other words, Purdue falsely or deceptively represented that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids. Purdue knowingly and willingly, unfairly and deceptively worked to turn evidence of addiction into an excuse to sell and prescribe even more drugs.

1258. Purdue’s misleading messages and materials were part of a broader strategy to convince prescribers to use opioids to treat their patients’ pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Coos County As described above in the context of Purdue’s Co-Defendants, nationwide messages reached Coos County prescribers and consumers in a number of ways, including, but not limited to, the following means and methods:

- a. they were carried into Coos County by Purdue’s sales representatives during detailing visits;
- b. they were made available to Coos County patients and prescribers through websites and ads, including ads in prominent medical journals; and
- c. they were delivered to Coos County prescribers by Purdue’s paid speakers, who were required by Purdue policy and by FDA regulations to stay true to Purdue’s nationwide messaging.

b. Purdue’s Deceptive Third-Party Statements

1259. Purdue’s unlawful or deceptive marketing efforts were not limited to making false or misleading representations through its own sales force for its own branded and unbranded

marketing materials. As referenced throughout, Purdue knew that regulatory constraints restricted what it could say about its drugs through direct marketing. Like the other Manufacturer Defendants, Purdue unlawfully or deceptively enlisted the help of third parties to release misleading information about opioids to circumvent regulatory constraints. The most prominent of these was APF.

i. *APF*

a) Purdue's Control of APF

1260. APF published and disseminated many of the most blatant falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, is described in detail below.

1261. Purdue unlawfully or deceptively exercised its dominance over APF through many projects and years. Purdue was APF's second-biggest benefactor with donations totaling \$1.7 million. In conjunction with the donations, Purdue notified APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." This messaging was intended to and did make clear to APF that Purdue's continued funding depended upon it continuing to support Purdue's business interests.

1262. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue made clear that the role APF could play would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups to which, upon information and belief, APF reached out. Purdue personnel

remained in constant contact with their counterparts at APF to ensure that this unlawful or deceptive relationship continued.

1263. This bogus alignment of interests was expressed most forcefully through Purdue's hiring of APF to provide consulting services on its marketing initiatives. Purdue and APF unlawfully or deceptively entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement unlawfully or deceptively gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to receive continuous actual knowledge of the false or deceptive representations that APF was disseminating on Purdue's behalf that related to the use of opioids to treat chronic pain. The agreement gave Purdue—but not APF—the right to end the project and APF's funding for any reason. This agreement demonstrates APF's lack of independence and its willingness to surrender to Purdue's control and commercial interests, which would have carried across all APF's work.

1264. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright.

1265. Purdue's ability to deploy APF on this project illustrates the degree of control it exercised over APF.

1266. In 2011, Purdue hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue paid this APF consultant \$7,500 in fees and expenses for 26 hours of work. Purdue later required this consultant to "to discuss and rehearse the delivery of [Purdue's]

campaign messages” and Purdue required that “message points will be provided to the Consultant in advance and discussed on a planned call.” At all times relevant to this complaint, decisions regarding the final content on the *Partners Against Pain* website were “at the sole discretion of Purdue.”

1267. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson for the launch of one of Purdue’s opioid-related projects, *Understanding & Coping with Lower Back Pain*.

1268. *Understanding & Coping with Lower Back Pain* appeared on the *Partners Against Pain* website. One of the consultants was APF’s paid employee, Mickie Brown. The consultant’s services were to be provided for a \$10,000 consulting fee for APF and \$1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances were reviewed and approved by individuals working for Purdue. It was not until later that APF worried about “how Purdue sees this program fitting in with our [existing] grant request.”

1269. In the context of the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue’s control at all relevant times with respect to *Partners Against Pain*.

1270. APF acquiesced to Purdue’s frequent requests that APF provide “patient representatives” for *Partners against Pain*.

1271. APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appeared on *Inthefaceofpain.com* as “Voices of Hope”— “champions passionate about making a difference in the lives of people who live with pain” and providing “inspiration and encouragement” to pain patients. APF also contracted with Purdue for a project

on back pain in which, among other things, it provided a patient representative who agreed to attend a Purdue-run “media training session.”

1272. According to an Assurance of Voluntary Compliance (“AVC”) entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. With the exception of one document linked to the website, *Inthefaceofpain.com* deceptively makes no mention of opioid abuse or addiction. Purdue’s copyright appears at the bottom of each page of the website, indicating its ownership and control of its content.

1273. There is no other indication that eleven of the individuals who provided testimonials on *Inthefaceofpain.com* received payments of \$231,000 for their participation in speakers’ programs, advisory meetings and travel costs between 2008 and 2013. The New York Attorney General found Purdue’s failure to disclose its financial connections with these individuals had the potential to mislead consumers.

1274. Nowhere was Purdue’s influence over APF so pronounced as it was with the APF’s “Pain Care Forum” (“PCF”). PCF was and continues to be run not by APF, but by Purdue’s in-house lobbyist, Burt Rosen. As described by a former drug company employee, Rosen exercised full control of PCF, telling them “what to do and how to do it.” This control allowed him, in turn, to run APF as, in accordance with Rosen’s thinking, “PCF was APF, which was Purdue.” PCF meets regularly in-person and via teleconference, and shares information through an email listserv.

1275. In 2011, APF and another third-party advocacy group, the Center for Practical Bioethics, were considering working together on a project. Having reviewed a draft document provided by the Center for Practical Bioethics, the APF employee cautioned that “this effort will be in cooperation with the efforts of the PCF” and acknowledged that “I know you have

reservations about the PCF and pharma involvement, but I do believe working with them and keeping the lines of communications open is important.” The Center for Practical Bioethics CEO responded by indicating some confusion about whom to speak with, asking “[i]s Burt Rosen the official leader” and reflecting what other sources have confirmed.

1276. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Alpharma, and allied Front Groups APF and ACPA (self-described as “industry-funded” groups), developed an unlawful or deceptive plan to address a perceived “lack of coordination” among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop together simplified “key” messages” to use for public education purposes. Their messages were reflected in programs like NIPC’s *Let’s Talk Pain* (put together by Endo and APF), and Purdue’s *In the Face of Pain*.

1277. When the FDA required drug companies to fund CMEs related to opioid risks in accordance with its 2009 REMS, Purdue, along with these Front Groups, worked through the PCF to ensure that, although it was mandatory for drug companies to fund these CMEs, it would not be mandatory for prescribers to attend them.

1278. A survey was circulated among Defendants Endo, Janssen, and Purdue, which predicted that the rates of doctors who would prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required in accordance with the REMS. With a push from PCF, acting under Purdue’s direction, the CMEs were not made mandatory for prescribers.

1279. APF showed its indebtedness to Purdue and its willingness to serve Purdue’s corporate agenda when APF chairman Dr. James N. Campbell testified on the company’s behalf

at a July 2007 hearing before the Senate Judiciary Committee “evaluating the propriety and adequacy of the OxyContin criminal settlement.”¹⁵⁷

1280. Despite its purported role as a patient advocacy organization, APF regularly overlooked substantial evidence that Purdue falsely told physicians and patients that OxyContin was “rarely” addictive and less addictive than other opioids. Like Purdue, APF disregarded its actual knowledge as to the truth about opioids and parroted Purdue’s deceptive messaging.

1281. Dr. Campbell falsely testified that addiction was a “rare problem” for chronic pain patients and asserted: “[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug.” There was, and is, no scientific support for those false and unsupportable statements.

1282. In furtherance of this unlawful or deceptive conspiracy, APF President Will Rowe reached out to Defendants, including Purdue, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine.

1283. APF’s pro-opioid publications were controlled and shaped by Purdue. These publications had no basis in science and were driven by the commercial interests of pharmaceutical companies - Purdue chief among them.

b) A Policymaker’s Guide

¹⁵⁷ *Evaluating the Propriety and Adequacy of the Oxycontin Criminal Settlement: Before the S. Comm. On the Judiciary*, 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF). Purdue was also able to exert control over APF through its relationships with APF’s leadership. Purdue-sponsored KOLs Russell Portenoy and Scott Fishman chaired APF’s board. Another APF board member, Perry Fine, also received consulting fees from Purdue. APF board member Lisa Weiss was an employee of a public relations firm that worked for both Purdue and APF. Weiss, in her dual capacity, helped vet the content of the Purdue-sponsored *Policymaker’s Guide*, which is described below.

1284. Purdue provided significant funding to and was involved with APF's creation and dissemination of *A Policymaker's Guide to Understanding Pain & Its Management* (the "*Policymaker's Guide*"), originally published in 2011 and still available online.¹⁵⁸ The *Policymaker's Guide* deceptively and falsely represented that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

1285. Specifically, the *Policymaker's Guide* falsely claimed that "multiple clinical studies" demonstrated that "opioids . . . are effective in improving daily function, psychological health and overall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement.

1286. The study cited in support of this claim specifically noted *that there were no studies demonstrating the safety of opioids long-term* and noted that "for functional outcomes, the other studied analgesics were significantly more effective than were opioids."¹⁵⁹

1287. The *Policymaker's Guide* also falsely or deceptively represented the risk of addiction. It deceptively or falsely claimed that pain had generally been "undertreated" due to [misconceptions about opioid addiction] and that "less than 1% of children treated with opioids become addicted."

1288. Moreover, the *Policymaker's Guide* wrongfully attempted to distract doctors from their patients' drug-seeking behavior by labeling it as "pseudoaddiction," which, according to the guide, "describes patient behaviors that may occur when pain is undertreated." Like *Partners Against Pain*, *A Policymaker's Guide* falsely noted that "pseudo-addiction can be distinguished

¹⁵⁸ <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last visited August 8, 2018).

¹⁵⁹ Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

from true addiction in that this behavior ceases when pain is effectively treated.” The similarity between these messages regarding “pseudoaddiction” highlights the common, concerted effort behind Purdue’s deceptive statements.

1289. The *Policymaker’s Guide* falsely represented the safety of increasing doses of opioids and deceptively minimized the risk of withdrawal. For example, the *Policymaker’s Guide* claimed that “symptoms of physical dependence” on opioids in long-term patients “can often be ameliorated by gradually decreasing the dose of medication during discontinuation” while omitting the significant hardship that often accompanies cessation of use. Similarly, the *Policymaker’s Guide* falsely represented that even indefinite dose escalations are “sometimes necessary” to reach adequate levels of pain relief while completely omitting the safety risks associated with increased doses.

1290. Purdue provided substantial monetary assistance toward the creation and dissemination of the *Policymaker’s Guide*, providing APF with \$26,000 in grant money. APF ultimately disseminated the *Policymaker’s Guide* on behalf of Defendants, including Purdue. Purdue was kept in the loop through the development of the content of the guide. The periodic reports APF provided to Purdue regarding its progress on the *Policymaker’s Guide* establish that Purdue had editorial input on the contents.

1291. The *Policymaker’s Guide* was posted online and was available to, and intended to, and did, reach Coos County prescribers and consumers. As described below, the deceptive statements in *Policymaker’s Guide* regarding addiction and functionality were the very same messages Purdue directed at Coos County through its own sales force.

c) Treatment Options: A Guide for People Living with Pain

1292. Purdue's partnership with APF did not end with the *Policymaker's Guide*. Purdue also substantially assisted APF by beginning to sponsor *Treatment Options: A Guide for People Living with Pain* ("*Treatment Options*") in 2007. Based on Purdue's control of other APF projects, Purdue also would have exercised control over *Treatment Options*.

1293. *Treatment Options* is rife with false or misleading representations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresents that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve." There is absolutely no scientific support for this position.

1294. Further, as outlined above, *Treatment Options* falsely claims that addiction is rare and that, when it does occur, it involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, painting a narrow and misleading portrait of opioid addiction.

1295. *Treatment Options* also deceptively promotes the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs.

1296. *Treatment Options* notes that NSAIDs can be dangerous at high doses and falsely or deceptively inflates the number of deaths associated with NSAID use, distinguishing opioids as having less risk.

1297. *Treatment Options* also falsely or deceptively represents NSAIDs are different from opioids because, among other things:

- a. opioids have "no ceiling dose";
- b. this lack of ceiling is considered to be beneficial as some patients "need" larger doses of painkillers than they are currently prescribed; and

c. the risks associated with NSAID use increased if NSAIDs are “taken for more than a period of months,” but deceptively omits any similar warning about the risks associated with the long-term use of opioids.

1298. *Treatment Options* was posted online and remains online today. It was intended to and did reach Coos County prescribers and patients. As referenced herein, the deceptive statements in *Treatment Options* regarding addiction and functionality echo the messages Purdue directed at Coos County through its own sales force.

1299. Purdue also engaged in other promotional projects with and through APF and other allies. One such project was the publication and distribution of *Exit Wounds*, which, as described herein, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

1300. Purdue and APF provided each other with substantial assistance in distributing *Exit Wounds* and *Treatment Options* in Coos County and throughout the nation by providing grant money and other resources.

ii. *Purdue’s Work with Other Third-Party Front Groups and KOLs*

1301. Purdue also provided other third-party Front Groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

a) FSMB – Responsible Opioid Prescribing

In 2007, Purdue sponsored FSMB’s *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by Dr. Scott Fishman.

Purdue spent \$150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The deceptive or false contents of the book were distributed nationally and was intended to, and did, reach prescribers in Coos County.

b) AGS – Pharmacological Management of Persistent Pain in Older Persons

1302. Along with Janssen, Purdue worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As discussed throughout, these guidelines falsely or deceptively claimed that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse” as the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that “[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendation).”

1303. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines’ development could lead to allegations of bias and “the appearance of conflict.”

1304. AGS deceptively or unlawfully acted to eliminate “the root cause of that flack” by turning down commercial support to produce the 2009 Guidelines. In response to its determination that its veneer of independence would be tarnished if it accepted drug company money to create the content, AGS willfully and intentionally chose to circumvent transparency by developing the guidelines itself and turning to the drug companies for funding to *distribute* the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS’s “strategy that we will take commercial support to disseminate the 2009 Guidelines if such support is forthcoming.”

1305. AGS knew that it would not receive funding from Defendant Pharmaceutical Companies for distributing its guidelines unless the report was viewed favorably by Defendant opioid makers.

1306. AGS sought and obtained grants from Endo and Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons*. As a result, the publication was distributed nationally was intended to and did reach Coos County prescribers.

1307. Internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Purdue discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.¹⁶⁰

c) *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*

1308. Purdue sponsored a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes.

1309. The *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes* presentation falsely or deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME was presented at various locations in the United States and is available online today, including in Coos County.

d) *Managing Patient's Opioid Use: Balancing the Need and Risk*

1310. Purdue also sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation also falsely

¹⁶⁰ As described above, Purdue also provided substantial support for the AAPM/APS guidelines. The 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and fourteen out of twenty-one panel members who drafted the AAPM/APS Guidelines received support from Defendants Janssen, Cephalon, Endo, and Purdue.

or deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.” At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster’s Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to, and did, reach Coos County prescribers.

e) *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*

1311. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* (“*Path of the Patient*”) that was devoted entirely to the message of treating chronic pain with opioids. Although the program purported to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it certainly did not.

1312. This “educational” program, addressing treatment of a population known to be particularly susceptible to opioid addiction, failed to present any of the alternative treatment options available to younger adults and only discussed treatment of chronic pain with opioids.

1313. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient’s early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator falsely notes that, because of pseudoaddiction, the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor in the role-play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to, and did, reach Coos County prescribers.

f) *Overview of Management Options*

1314. Purdue also sponsored a CME titled *Overview of Management Options* issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which is still available for CME credit).

1315. The *Overview of Management Options* CME was edited by KOL Russel Portenoy, among others. It falsely or deceptively instructs physicians that NSAIDs and other drugs, excluding opioids, are unsafe at high doses.

1316. The data actually indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs.

1317. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online in the United States and was available to Coos County prescribers.

iii. *Purdue's Misleading Science*

1318. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a false or deceptive way.

1319. In 1998 Purdue funded two articles by Dr. Lawrence Robbins that showed that between 8% and 13% of the patients he studied became addicted to opioids. This was a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.¹⁶¹

1320. Purdue deceptively had these articles placed in headache-specific journals where they would be less likely to be encountered by pain specialists or general practitioners. The first

¹⁶¹ Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

of these articles has been cited a mere sixteen times; the second does not even appear on Google scholar.

1321. Five years later, Purdue funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding the fact that aforementioned Purdue-funded studies that tested Purdue's own drugs had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the scientifically unsupported and contextually irrelevant 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive.

1322. This article was placed in a prominent pain journal and has been cited 487 times.¹⁶² While this article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

c. Purdue's Deceptive Statements to Coos County Prescribers and Patients

1323. Purdue directed the dissemination of the false or misleading statements described herein to Coos County prescribers and patients, including, but not limited to, the following means and methods:

- a. the Front Groups
- b. KOLs;
- c. the publications referenced herein;
- d. its sales force in Coos County; and
- e. advertisements in prominent medical journals.

¹⁶² C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 Pain 71 (2003).

1324. The false or deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the benefits of Purdue's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

1325. The false or deceptive message that OxyContin provided 12 hours of pain relief was intended to and did reach Coos County prescribers through nationally circulated advertising.

1326. The false or deceptive message that OxyContin provided 12 hours of pain relief was also carried directly into the offices of Coos County doctors by Purdue's sales representatives.

1327. The false or deceptive messages minimizing addiction were directed at Coos County patients and prescribers through the publications circulated and means referenced above.

1328. The false or deceptive messages minimizing addiction were also disseminated directly by Purdue's sales force.

1329. Purdue also used its sales force to disseminate false or misleading statements about the ability of opioids to improve functionality.

1330. Purdue's national marketing campaign included the false or deceptive representations described throughout in the context of the descriptions of the other Defendants conduct.

1331. Through Purdue's national marketing campaign, the company disseminated the false and deceptive representations referenced throughout to Coos County prescribers and consumers.

1332. In particular, prescriber accounts reflect that Purdue detailers:

a. omitted or minimized the risk of opioid addiction;

- b. claimed that Purdue's drugs would be less problematic for patients because they had extended release mechanisms, were tamper proof, and were "steady state";
- c. claimed that OxyContin would provide 12 hours of pain relief;
- d. represented that screening tools could help manage the risk of addiction;
- e. minimized the symptoms of withdrawal;
- f. claimed or implied that opioids were safer than NSAIDs; and
- g. overstated the benefits of opioids, including by making claims of improved function.

1333. A survey of physician who reported the messages that they retained from detailing visits and other promotional activity establishes Purdue sales representatives from at least between 2008 and 2012 represented OxyContin as:

- a. being effective for a full 12 hours;
- b. improving patients' sleep;
- c. prevented illegal drug use;
- d. was formulated to be 'less addicting';
- e. harder to adulterate; or
- f. reduced patient "buzz.

1334. Purdue sales representatives also represented OxyContin as improving patients' sleep to an orthopedic surgeon in 2006 and to a physicians' assistant in 2013.

1335. At times relevant to this complaint, Purdue sales representatives were instructed by Purdue to represent that OxyContin improves patients' sleep

1336. At all times relevant to this complaint, any representation that Oxycontin improves patients sleep were unsubstantiated or not based on scientific research.

1337. At times relevant to this complaint, Purdue sales representatives were instructed by Purdue to represent to internists that the reformulation of OxyContin prevented illegal drug use and that the formulation was ‘less addicting’ rather than being harder to adulterate.

1338. At all times relevant to this complaint, any representation that Oxycontin was less addicting were unsubstantiated or not based on scientific research.

1339. At times relevant to this complaint, Purdue sales representatives were instructed by Purdue to represent that the sustained-release property of OxyContin reduced patient “buzz”.

1340. At all times relevant to this complaint, any representation that reduced patient buzz were unsubstantiated or not based on scientific research.

1341. At times relevant to this complaint, Purdue sales representatives were instructed by Purdue to represent represented its Schedule III opioid Butrans as having low or little abuse potential.

1342. At all times relevant to this complaint, any representation that its Schedule III opioid Butrans had low or little abuse potential were unsubstantiated or not based on scientific research.

6. Insys

1343. Insys was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur “known for applying aggressive marketing tactics and sharp price increases on older drugs.”¹⁶³

¹⁶³ U.S. senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal, Nov. 22, 2016, available at www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968).

1344. In 2012, Insys received U.S. Food and Drug Administration approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain.

1345. Insys encountered significant obstacles marketing Subsys because insurers employed a process known as prior authorization.

1346. Prior authorization prevents the over prescription and abuse of powerful and expensive drugs.

1347. The prior authorization process requires “additional approval from an insurer or its pharmacy benefit manager before dispensing” and may also impose step therapy which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.¹⁶⁴

1348. Insys circumvented this process by forming a prior authorization unit, known at one point as the Insys Reimbursement Center (“IRC”).

1349. The Insys Reimbursement Center facilitated the process of using aggressive and deceptive or illegal marketing techniques.

1350. Insys published education articles that falsely praised their products’ non-addictive nature.

1351. Insys deceptively or wrongfully funded patient advocacy groups who unknowingly promoted Insys’ agenda of raising the profile of pain so that drugs could be prescribed to treat it.

¹⁶⁴ Senate Permanent Subcommittee on Investigations, *Combating the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems*; see also Department of Health and Human Services, Centers for Medicare & Medicaid Services, *How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage Use Pharmacies, Formularies, & Common Coverage Rules*.

1352. Motivated by corporate greed, Insys' former sales representatives unlawfully paid off medical practitioners to prescribe Subsys whether any medical need existed or not.¹⁶⁵

1353. Insys employees were pressured internally and received significant monetary incentives to increase the rate of prescription approvals.¹⁶⁶

1354. According to a federal indictment and ongoing congressional investigation by Sen. Claire McCaskill, IRC employees unlawfully pretended to be with doctors' offices and falsified medical histories of patients. The report, acquired by McCaskill's investigators, includes transcripts and an audio recording of employees unlawfully or deceptively implementing these techniques to obtain authorization from insurers and pharmacy benefit managers. The transcript actually includes uncontradicted evidence that an Insys employee pretending to call on behalf of a doctor and inaccurately described the patient's medical history.¹⁶⁷

1355. While marketing its addictive product, Insys employees also unlawfully or deceptively created the impression that the patient had cancer, without explicitly saying so, because cancer was a requirement for prior clearance to prescribe Subsys. Insys was warned by a consultant that it lacked needed policies for governing such activities and after being warned and receiving actual notice of what was occurring, Insys executives did not implement corrective internal procedures.

¹⁶⁵ Lopez, Linette. "It's been a brutal week for the most shameless company in the opioid crisis- and it's about to get worse," *Business Insider*, <http://www.businessinsider.com/opioid-addiction-drugmaker-insys-arrests-justice-department-action-2017-7>

¹⁶⁶ Boyd, Roddy. *Murder Incorporated: Insys Therapeutics. Part I*. Southern Investigative Reporting Foundation. <http://sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/>; see also Indictment. *United States v. Babich, et al.*, D. Mass. (No. 1;16 CR 10343).

¹⁶⁷ U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization*, at pp. 7-10.

1356. A class action lawsuit against Insys revealed that its management “was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients”.

1357. An Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by Insys on behalf of Oregon patients were for off-label uses.¹⁶⁸

1358. Physicians are allowed to prescribe medications for indications outside of FDA guidelines as they deem fit in their professional judgement, but it is illegal for pharmaceutical companies to market a drug for off-label use.

1359. In 2008, biopharmaceutical company Cephalon settled with the U.S. government for \$425 million in a suit against the company that alleged it marketed drugs for unapproved uses (off-label). The FDA approved the drugs in issue only for opioid tolerant cancer patients.

1360. According to the Oregon settlement and class-action lawsuit, at least three employees involved in sales and/or marketing at Cephalon had moved over to Insys Therapeutics.¹⁶⁹

1361. Additionally, Insys created a “legal speaker program” which turned out to be an unlawful or deceptive scam. The Justice Department commented on the program and stated:

The Speaker Programs, which were typically held at high-end restaurants, were ostensibly designed to gather licensed healthcare professionals who had the capacity to prescribe Subsys and educate them about the drug. In truth, the events were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and no educational component took place. “Speakers” were paid a fee that ranged from \$1,000 to several thousand dollars for attending these dinners. At times, the sign-in sheets for the Speaker Programs were forged so as to make it appear that the programs had an appropriate audience of healthcare professionals.

¹⁶⁸ Gusovsky, Dina. *The Pain Killer: A Drug Company Putting Profits Above Patients*, CNBC (<https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html>).

¹⁶⁹ *Id.*

1362. Insys paid hundreds of thousands of dollars to doctors in exchange for prescribing Subsys.

1363. Three top Insys prescribers have already been convicted of taking bribes.

1364. Fentanyl products are considered to be the most potent and dangerous opioids on the market.

1365. Fentanyl products are up to 50 times more powerful than heroine.¹⁷⁰

1366. In an internal presentation dated 2012 and entitles, “2013 SUBSYS Brand Plan,” Insys identified one of six “key strategic imperatives” as “Mitigate Prior Authorization barriers.”¹⁷¹ On a later slide, the company identified several tasks associated with this effort, including “Build internal prior authorization assistance infrastructure,” “Establish an internal 1-800 reimbursement assistance hotline,” and “Educate field force on prior authorization process and facilitation.”¹⁷²

1367. Additional materials produced by Insys to the minority staff establish that Insys did not match these efforts with compliance processes sufficient to prevent fraud and that Insys was internally aware and had actual knowledge of the danger of the problematic practices referenced herein.

1368. On February 18, 2014, Compliance Implementation Services (“CIS”), a healthcare consultant, issued a draft report to Insys titled, “Insys Call Note, Email, & IRC Verbatim Data

¹⁷⁰ U.S. Department of Justice. Drug Enforcement Administration. *A Real Threat to Law Enforcement: Fentanyl*. [https://www.dea.gov/druginfo/DEA%20Targets%20Fentanyl%20%20A%20Real%20Threat%20to%20Law%20Enforcement%20\(2016\).pdf](https://www.dea.gov/druginfo/DEA%20Targets%20Fentanyl%20%20A%20Real%20Threat%20to%20Law%20Enforcement%20(2016).pdf).

¹⁷¹ U.S. senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting Insys Therapeutics, Inc., *2013 Subsys Brand Plan, 2012 Assessment* (2012) (INSYS_HSGAC_00007472)).

¹⁷² *Id.* at INSYS_HSGAC_00007765.

Audit Report.”¹⁷³ The introduction to the report explained that “CIS was approached by INSYS’ legal representative ... on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented.”¹⁷⁴ Insys had expressed concerns “with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements.”¹⁷⁵ An additional concern “stemmed from the lack of monitoring of commercial activities where these types of interactions could occur.”¹⁷⁶

1369. Given these issues, Insys requested that CIS in part review “the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers ... to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS’ commercially marketed product.”¹⁷⁷

1370. According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, “no formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or

¹⁷³ U.S. senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting Compliance Implementation Services, Insys Call Note, Email & IRC Verbatim Data Audit Report (Feb. 18, 2014) (INSYS_HSGAC_00007763)).

¹⁷⁴ *Id.* at INSYS_HSGAC_00007765.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

patients exists...that governs the support function of obtaining a prior authorization for the use of SUBSYS.”¹⁷⁸

1371. In addition, the CIS report noted that “there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC.”¹⁷⁹

1372. In fact, “the majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast.”¹⁸⁰

1373. Although four informal standard operating procedures existed with regarded to IRC functions, these documents “lacked a formal review and approval” and failed to “outline appropriately the actions performed within the IRC.”¹⁸¹

1374. The CIS report also explains that Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to the CIS report “no formal, documented, or detailed processes by which IRC representatives’ calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner.”¹⁸²

¹⁷⁸ *Id.* at INSYS_HSGAC_00007770.

¹⁷⁹ *Id.* at INSYS_HSGAC_00007768.

¹⁸⁰ *Id.* at INSYS_HSGAC_00007771.

¹⁸¹ *Id.* at INSYS_HSGAC_00007770.

¹⁸² *Id.* at INSYS_HSGAC_00007769.

1375. More broadly, the report notes that Insys had “no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients.”¹⁸³

1376. At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management “formally draft and obtain proper review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs.”¹⁸⁴

1377. Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures “specific to each job function within the IRC,” accompanied by “adequate training and understanding of these processes.”¹⁸⁵ To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow management “to monitor both live and anonymously IRC employee communications both incoming and outgoing.”¹⁸⁶ Finally, CIS recommended that Insys institute a formal process for revising and updating “IRC documentation used for patient and HCP data.”¹⁸⁷

1378. The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers revealed “that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated.”¹⁸⁸

¹⁸³ *Id.* at INSYS_HSGAC_00007771.

¹⁸⁴ *Id.* at INSYS_HSGAC_00007770.

¹⁸⁵ *Id.* at INSYS_HSGAC_00007771.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at INSYS_HSGAC_00007772.

1379. Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee's affiliation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

1380. One former Insys sales representative described the motto of this approach to patients as "Start them high and hope they don't die."¹⁸⁹

7. Mallinckrodt

1381. Mallinckrodt is a pharmaceutical manufacturer and one of the largest manufacturers of oxycodone.

1382. On July 11, 2017, Mallinckrodt agreed to pay \$35 million to settle allegations that it violated the law.¹⁹⁰ Mallinckrodt's acts violate New Hampshire law.

1383. The settlement addressed Mallinckrodt's failure to meet its obligations to detect and notify the DEA of suspicious orders of controlled substances such as oxycodone and violations in the Mallinckrodt's manufacturing batch records at its plant in Hobart, New York.¹⁹¹

1384. The DOJ stated, "Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street."¹⁹²

¹⁸⁹ Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.*, No. 2:14-cv-01043-GMS, Dkt. 41 (D. Ariz. Oct. 27, 2014).

¹⁹⁰ <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

¹⁹¹ *Id.*

¹⁹² *Id.*

1385. The government alleged that Mallinckrodt failed to design and implement an effective system to detect and report “suspicious orders” for controlled substances – orders that are unusual in their frequency, size, or other patterns.

1386. From 2008 until 2011, the U.S. alleged, Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.¹⁹³

1387. The government also alleged that Mallinckrodt violated record keeping requirements at its manufacturing facility in upstate New York. Among other things, these violations created discrepancies between the actual number of tablets manufactured in a batch and the number of tablets Mallinckrodt reported on its records. Accurate reconciliation of records at the manufacturing stage is a critical first step in ensuring that controlled substances are accounted for properly through the supply chain.¹⁹⁴

F. The Result of Defendants’ Fraudulent Scheme

1388. Through their direct unlawful or deceptive Marketing Efforts, along with those of the Front Groups and KOLs they assisted and controlled including the use of seemingly objective materials they distributed, Manufacturer Defendants accomplished exactly what they set out to do - they changed the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, Coos County doctors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to such Defendants’ campaign.

¹⁹³ *Id.*

¹⁹⁴ *Id.*

1389. But for the misleading information disseminated by Manufacturer Defendants, doctors would not, in many instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

1. Manufacturer Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Coos County.

1390. In the first instance, Coos County was damaged directly, through its payments of false claims for chronic opioid therapy by (a) partially funding a medical insurance plan for its employees and (b) its workers' compensation program.

1391. Manufacturer Defendants' Marketing Efforts caused health care providers to prescribe, and Coos County, through partially funding a medical insurance plan for its employees and its workers' compensation program, to pay for prescriptions of opioids to treat chronic pain.

1392. As a result of the Manufacturer Defendants' branded and unbranded marketing, health care providers wrote and the County paid for prescriptions of opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. These prescriptions were caused by such Defendants' fraudulent Marketing Efforts and therefore all of them constitute false claims. Coos County is obligated to cover medically necessary and reasonably required care and it had no choice but to pay for these false and fraudulent claims.

1393. The fact that Coos County would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Manufacturer Defendants' fraudulent, unlawful or deceptive Marketing Efforts.

1394. Manufacturer Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, and government payors such as Coos County, to pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the

contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

a. Increase in Opioid Prescribing Nationally

1395. The Manufacturer Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain was an unequivocal success.

1396. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide.

1397. During the year 2009, prescriptions filled by outpatient retail pharmacies rose to 257 million prescriptions for opioids nationwide.¹⁹⁵

1398. Opioid prescriptions increased even as the percentage of patients visiting doctors for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%.¹⁹⁶

1399. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids.

1400. Indeed, "opioids are the most common means of treatment for chronic pain."¹⁹⁷

1401. From 1980 to 2000, opioid prescriptions for chronic pain visits doubled.

1402. This resulted not from an epidemic of pain, but an epidemic of prescribing.

¹⁹⁵ Office of National Drug Control Policy, *2011 Prescription Drug Abuse Prevention Plan*, Whitehouse.gov, (no longer available on whitehouse.gov), <https://obamawhitehouse.archives.gov/ondcp/prescription-drug-abuse1>.

¹⁹⁶ Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).

¹⁹⁷ Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

1403. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications decreased.

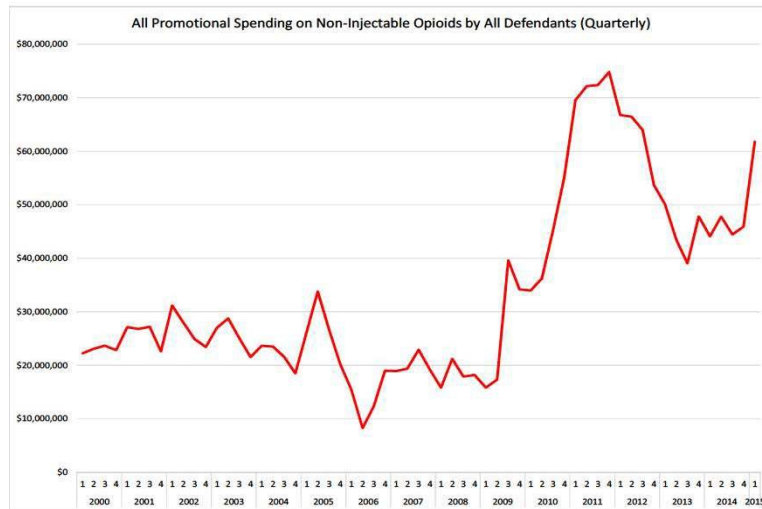
1404. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

1405. As a direct, proximate and foreseeable consequence of Manufacturer Defendants' Marketing Efforts and wrongful conduct, this increase corresponds with and was caused by Defendants' massive marketing push.

1406. As reflected in the chart below, according to data obtained from a marketing research company, Manufacturer Defendants' spending on marketing of opioids nationwide—including all of the drugs at issue here—stood at more than \$20 million per quarter and \$91 million annually in 2000.

1407. By 2011, that figure hit its peak of more than \$70 million per quarter and \$288 million annually, an increase of more than three-fold. By 2014, the figures dropped to roughly \$45 million per quarter and \$182 million annually, as Manufacturer Defendants confronted increasing concerns regarding opioid addiction, abuse, and diversion, and as Janssen, which accounted for most of the spending reduction, prepared to sell its U.S. rights to Nucynta and Nucynta ER.

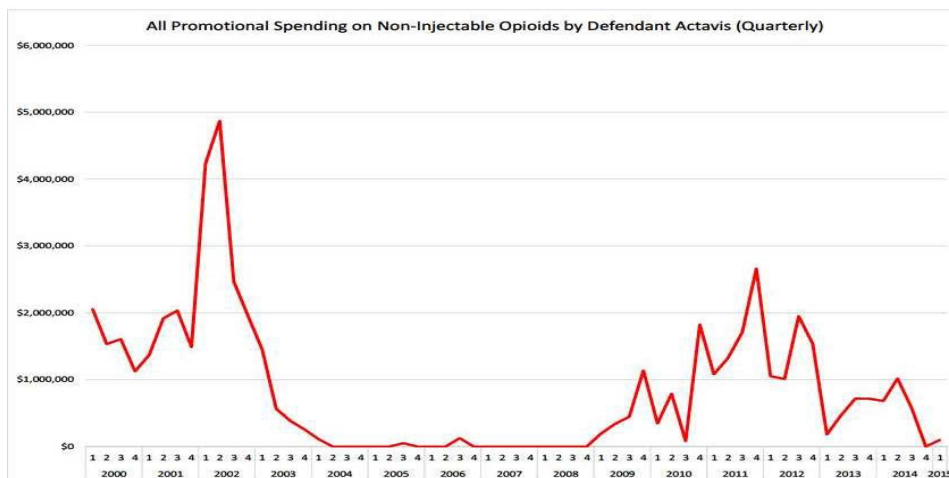
1408. Even so, Manufacturer Defendants still spent double what they had spent in 2000 on opioid marketing.



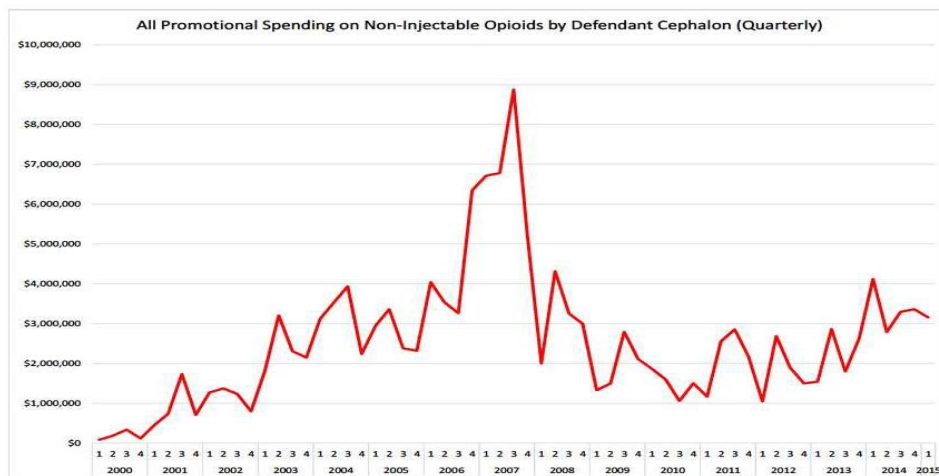
1409. Manufacturer Defendants' opioid detailing visits to individual doctors made up the largest component of this spending, with total detailing expenditures more than doubling between 2000 and 2014 to \$168 million annually.

1410. Each Manufacturer Defendant's promotional spending reflects its participation in this marketing blitz. Between 2000 and 2011:

- Actavis's promotional spending, which was virtually nonexistent in the 2004-2008 period, began to sharply rise 2009. The third quarter of 2011 saw a peak of \$3 million at one point in 2011 and nearly \$7 million for the year, as shown below:

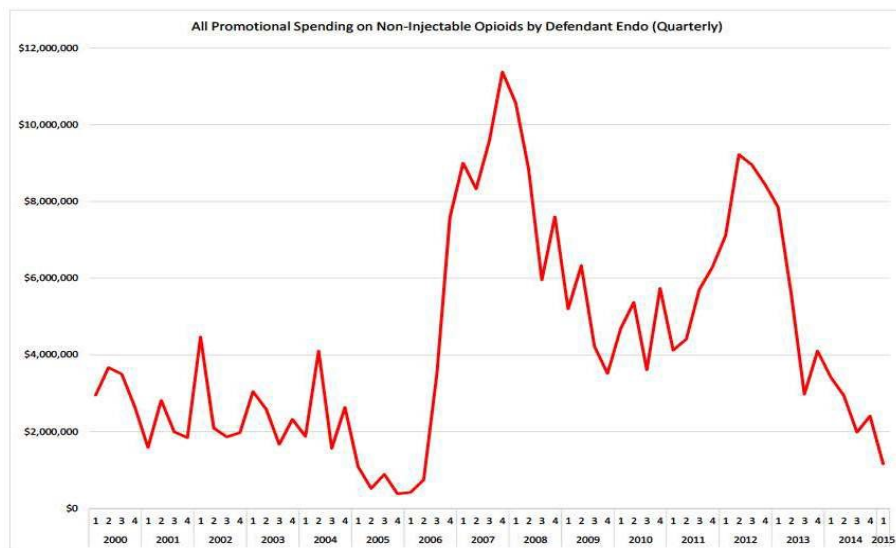


- Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$4 million in 2014 (and more than \$13 million for the year), including a peak, coinciding with the launch of Fentora, of nearly \$9 million halfway through 2007 (and more than \$27 million for the year), as shown below:

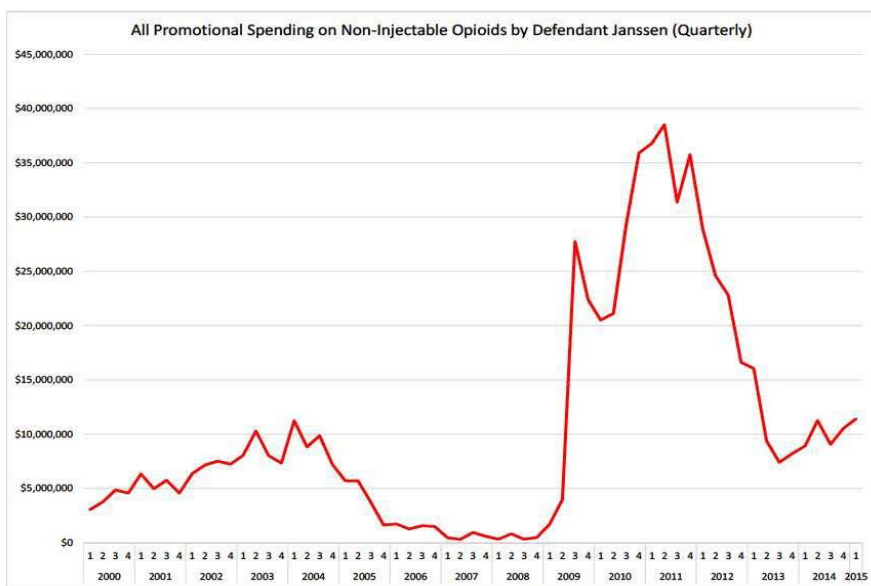


- Endo's quarterly spending went from the \$2 million to \$4 million range from 2000 to 2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8

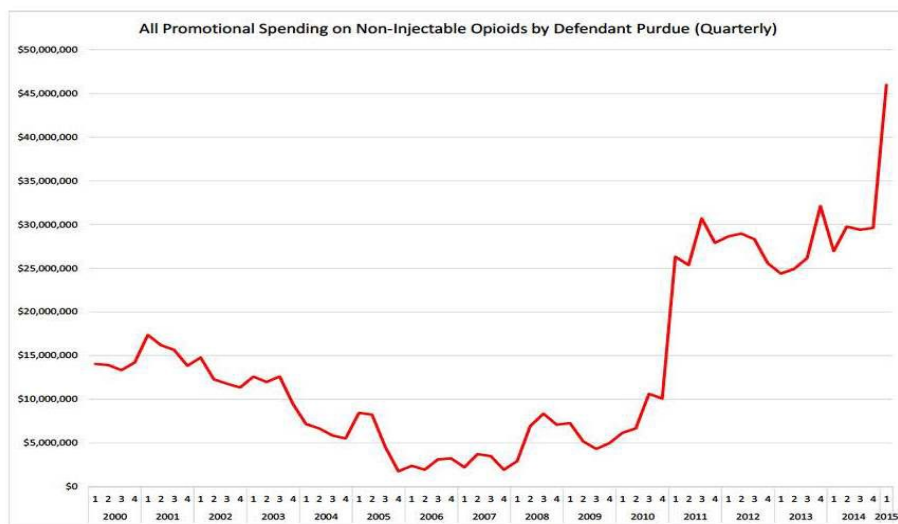
million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):



- Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011) as shown below:



- Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continued to rise, as shown below:



b. The County's Increased Spending on Opioids

1411. As a direct, proximate and foreseeable consequence of Manufacturer Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Manufacturer Defendants' deceptive Marketing Efforts. Plaintiff has incurred, and continues to incur, costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, law enforcement costs, substance abuse treatment costs, costs for treating overdose victims with drugs such as Narcan, and lost productivity costs. Manufacturer Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

i. Manufacturer Defendants' Misrepresentations Were Material

1412. Manufacturer Defendants' misrepresentations and Marketing Efforts were material to, and influenced, the County's decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, the County would not have been presented with, or paid, claims for opioids that would not have been written but for such Defendants' fraudulent and deceptive Marketing Efforts. Second, the County has demonstrated that such Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

1413. As laid out above, such Defendants' misrepresentations related to the County's requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under the County's health plans and workers' compensation program. But for such Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

1414. It is the County's practice not to pay claims that are not medically necessary or reasonably required. However, the County would not have known whether a prescriber had made an informed judgment that a particular claim for opioids was medically necessary or reasonably required, or, conversely had acted under the influence of such Defendants' fraudulent and deceptive Marketing Efforts. It is not clear from the face of a claim whether: (1) the patient suffered from cancer or another terminal condition, for example, where long-term prescribing was

medically necessary or appropriate; or (2) the prescriber was exposed to such Defendants' marketing materials, treatment guidelines, or education programs, or visited by a drug representative who engaged in affirmative misrepresentations or omissions, for example.

ii. *The County's Increased Costs Correlate with Defendants' Promotion*

1415. The County's opioid-related spending rose along with Manufacturer Defendants' spending to promote opioids. That spending had a direct impact on opioid use (and its consequences in abuse, addiction, and overdose) in Coos County

1416. It is also distressing (and a sign of further problems ahead) that the drop in opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in Manufacturer Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Coos County Consumers.

a. Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death

1417. In New Hampshire, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death.

1418. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse.

1419. "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."¹⁹⁸

1420. Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011. This is more than twice as many deaths as heroin and cocaine combined.

¹⁹⁸ Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

1421. Drug poisonings now exceed motor vehicle accidents as a cause of death.

1422. More Americans have died from opioid overdoses than from participation in the Vietnam War.

1423. Contrary to Manufacturer Defendants' false or deceptive representations, most of the illicit use stems from *prescribed* opioids.

1424. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

1425. Opioid patients who take low-dose opioids from a single prescriber are not illicit users or "doctor-shoppers."

1426. According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber account for 20% of all prescription drug overdoses.

1427. Death statistics represent only the tip of the iceberg.

1428. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

1429. Emergency room visits tied to opioid use likewise have sharply increased in Coos County.

1430. Widespread opioid use and abuse in Coos is a problem even when it does not result in injury or death.

1431. Opioid addiction affects residents of all ages, ethnicities, and socio-economic backgrounds in Coos County

1432. Many addicts start with a legal opioid prescription for conditions such as chronic back pain, fibromyalgia, or even dental pain and do not realize they are addicted until they cannot stop taking the drugs.

1433. As referenced above, glaring omissions relating to the risks and adverse effects of opioid use described consistently by counselors and patients, mirror and confirm Manufacturer Defendants' drug representatives' own widespread practice.

b. Increased Opioid Use Has Increased Costs Related to Addiction Treatment

1434. Coos County has opioid treatment programs, Substance Alternative Clinics, that provide a comprehensive treatment program for persons addicted to heroin or other opioids.

1435. In addition to intense counseling Coos County offers a wide range treatment programs and ancillary services related to opioid addiction.

1436. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction—buprenorphine/naloxone and naltrexone—were written and paid for nationwide. Many were in Coos County.

1437. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors to be \$72.5 billion.

c. Increased Opioid Use Has Fueled an Illegal Secondary Market for Narcotics and the Criminals Who Support It

1438. Manufacturer Defendants' success in expanding the opioid market to new patients and chronic conditions created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

1439. Manufacturer Defendants' scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them.

1440. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a “substantial increase in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use.”¹⁹⁹

1441. It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors’ prescriptions.

1442. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

1443. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin.

1444. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals.

1445. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006.

1446. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official, “Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . that is the reality we’re facing.”²⁰⁰

1447. That reality is true in Coos County.

¹⁹⁹ G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) JAMA 1865 (2012).

²⁰⁰ Matt Pearce & Tina Susman, *Philip Seymour Hoffman’s death calls attention to rise in heroin use*, L.A. Times, Feb. 3, 2014, <http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204>.

1448. According to addiction programs in the County and across New England, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

3. Defendants' Fraudulent Marketing Has Led to Record Profits

1449. While the use of opioids has taken an enormous toll on the County and its residents, Manufacturer Defendants have gained blockbuster profits.

1450. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers²⁰¹—roughly one prescription per American adult. Opioids generated \$8 billion in revenue for drug companies just in 2010.

1451. Financial information—where available—indicates that Manufacturer Defendants each experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above.

1452. Purdue's OxyContin sales alone increased from \$45 million in 1996 to \$3.1 billion in 2010.

²⁰¹ Press Release, Center for Disease Control, Opioid painkiller prescribing varies widely among states: Where you live makes a difference (July 1, 2014), <https://www.cdc.gov/media/releases/2014/p0701-opioid-painkiller.html>.

1453. In 2010, research firm Frost & Sullivan projected an increase to \$15.3 billion in overall revenue from opioid sales by 2016.

4. Manufacturer Defendants Fraudulently Concealed Their Misrepresentations

1454. At all times relevant to this complaint, Manufacturer Defendants took steps to avoid detection of, and fraudulently conceal, their deceptive marketing and conspiratorial behavior.

1455. First, and most prominently, Manufacturer Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Such Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

1456. While Manufacturer Defendants were listed as sponsors of many of the publications described in this complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. As referenced throughout, such Defendants exerted their considerable influence on these promotional and “educational” materials.

1457. In addition to hiding their own role in generating the deceptive content, Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear as if they were accurate, truthful, and supported by substantial scientific evidence. Such Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions they did not actually support. The true lack of support Manufacturer Defendants’ deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Coos County.

1458. Thus, while the opioid epidemic was evident, Manufacturer Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it.

1459. Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that the County now asserts.

1460. The County was not alerted to the existence and scope of Manufacturer Defendants' industry-wide fraud and Marketing Efforts and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

1461. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the County of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

G. The Sackler Family with Their Cohorts on Purdue's Board of Directors and Its Corporate Officers Knowingly and Intentionally Engineered, Furthered and Profited from the Deceptive and Deadly Marketing of Opioids.

1462. The decades-long campaign of strategic marketing and other misinformation that created the opioid epidemic and its devastating effects began, in large measure, with the introduction of Oxycontin by Purdue in 1995.

1463. That campaign did not occur in a vacuum.

1464. That campaign was initiated, directed and overseen by a tightly-knit group of individuals who were in charge of Purdue. They include the Individual Purdue Defendants.

1465. Throughout the unlawful and deceptive Marketing Efforts, the Sackler family has dominated Purdue's Board of Directors, along with their complicit fellow board members and corporate officers.

1466. As a result of the blockbuster success of their unlawful, deceptive and unfair Marketing Efforts, the Sackler family, including the Sackler Family Defendants, has become one of the wealthiest families in the United States, with a collective net worth of \$14 billion.

1467. The other members of the Board of Directors, including the Additional Purdue Board Member Defendants, and the other complicit Individual Purdue Defendants, including the Purdue CEO Defendants, have also reaped the benefits of their successful Marketing Efforts and Purdue's mind-numbing profits through financial recompense for their activities.

1468. Each of the Individual Purdue Defendants had full knowledge of the unfair and deceptive Marketing Efforts and its devastating impact upon the health and well-being of its victims and their communities, yet they willfully and knowingly substantially assisted in its continuation and expansion and reaped its profits.

1469. Each of the Individual Purdue Defendants controlled Purdue's Marketing Efforts described above and herein.

1470. Each of the Individual Purdue Defendants sought to conceal the misconduct described above and herein.

1471. The Individual Purdue Defendants received money from and were and are primary financial beneficiaries of the unfair and deceptive Marketing Efforts and the resultant opioid epidemic.

1472. Through their control and assistance of Purdue's direct unlawful and deceptive Marketing Efforts, along with those of the Front Groups and KOLs that they assisted and controlled, the Individual Purdue Defendants accomplished exactly what they intended - they changed the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain.

1473. As a result, Coos County doctors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to such Defendants’ campaign.

1474. But for their wrongful and/or illegal conduct, doctors would not, in many instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain and the market for opioids would not have exponentially increased.

1475. The Individual Purdue Defendants are personally liable for the unfair and deceptive marketing campaign because they participated in it, oversaw and/or controlled; they knew about the illegal and tortious conduct and failed to cease it; and/or they should have known about such illegal and tortious conduct and failed to cease it. Under well-established New Hampshire law, they also aided and abetted.

1476. The Individual Purdue Defendants are also personally liable for the unlawful, unfair and deceptive acts and practices referenced herein, including, but not limited to, the Marketing Efforts, in part, because a director or officer is liable for the tortious acts of another corporate agent when the director or officer participates in that tortious conduct or with knowledge approves the tortious conduct.

1. The Sackler Family’s Founding of Purdue and their Integration of Medicine and Marketing.

1477. In 1952, brothers Arthur, Mortimer and Raymond Sackler, all physicians, purchased Purdue Frederick Company (which later changed its name to Purdue Pharma) (“PF Co.”), a small patent-medicine company.

1478. Eldest brother Arthur Sackler demonstrated a penchant for marketing from his early days. His obvious interest was established very early in his life by his activity choice and service as advertising manager of his high school newspaper. He later cemented and honed his skills in the art of marketing and advertising as a copywriter at a small advertising agency while pursuing

his medical degree. Of particular note, he thought enough of it that even in the context of his alternative career choice, all things considered, he eventually purchased that agency.

1479. Arthur Sackler's career was marked by a highly practiced skill for exploiting marketing and advertising with the sale of drugs. He put into practice his non-traditional belief that the most effective way to market a new drug was to target not the patient end-users, but the physicians writing the prescriptions, and with ads prominently featuring endorsements by fellow physicians.

1480. His adept skills at manipulation were recognized posthumously in 1997 with his induction into the Medical Advertising Hall of Fame. Officially he was remembered then for his "bringing the full power of advertising and promotion to pharmaceutical marketing." About that time something else began that he will be remembered for - the strategy that led to the Opioid crisis.

1481. As an adman, Arthur Sackler was a chief creative and motivating force behind the crafting of deceptive and immoral marketing of drugs to vulnerable populations, including the advertising of the drug Valium for common, non-medically approved conditions such as homesickness by college women.

1482. Arthur Sackler despicable marketing practices resulted in what Senator Edward Kennedy characterized as "a nightmare of dependence and addiction."

1483. Arthur Sackler's early despicable and immoral approach to marketing addictive drugs developed into a mode of operation and has since become a Sackler family trademark.

1484. The unethical effectiveness of the Sackler approach of bringing a product to market was first cited by another United States Senator in the 1960's.

1485. More specifically, a memo prepared by United States Senator Kefauver's staff contained the following conclusion:

"The Sackler empire is a completely integrated operation in that it can devise a new drug in its drug development enterprise, have the drug clinically tested and secure favorable reports on the drug from the various hospitals with which they have connections, conceive the advertising approach and prepare the actual advertising copy with which to promote the drug, have the clinical articles as well as advertising copy published in their own medical journals, [and] prepare and plant articles in newspapers and magazines."

1486. After his death in 1987, Arthur Sackler's unscrupulous and unlawful marketing techniques for addictive drugs were put to use and expanded upon. In fact they became an integral part of the Purdue's, including the Individual Purdue Defendants', Marketing Efforts for other drugs, and eventually Opioids and their related "profit centers".

1487. Founder Arthur Sackler's share in PF Co. was bought out by his two brothers after his death in 1987.

2. Purdue's Obscured Corporate Ownership and Governance

1488. Purdue is a privately held company which has intentionally acted to obscure its precise ownership and governance structures and practices. They carried out elaborate corporate structuring and "shell games", including share and profit distribution, to provide the Sackler Defendants insulation from liability and at the same time allow them the autonomy and freedom to unscrupulously and unlawfully act to callously maximize profits. The Sackler family has a well-established history of being self-centered profiteers, notwithstanding donations to various charities. Of note, not one penny of their charitable donations has gone toward funding rehabilitation or other restorative programs.

1489. Purdue is owned and controlled through a myriad of holding companies and family trusts, of which fifty percent is owned by the widow and descendants of Mortimer Sackler and the

other fifty percent by the widow and descendants Raymond Sackler (together, the “Sackler Families”).

1490. The Sackler Families, both directly and indirectly, are the primary owners of and control Purdue and its related entities. At all times, the Sackler Family Defendants controlled Purdue and its associated companies and held a majority of seats on their boards.

1491. Purdue Pharma Inc. is the managing general partner of Purdue Pharma L.P. and of many of the various Purdue-related entities.

1492. Purdue Pharma Inc. status as managing general partner of the various entities ensures Purdue Pharma Inc.’s control of those entities. In turn and at all relevant times to this complaint, the Sackler Families or Sackler-family related individuals control Purdue Pharma Inc. through their board memberships.

1493. The officers of Purdue Pharma Inc. reported to its board of directors, thereby ensuring the Sackler Families’ control over Purdue.

1494. At all times relevant, the Sackler Families possessed knowledge of the inner workings and decisions of Purdue and its related entities, in part, through receipt of all board reports. In a 1994 written directive, Jonathan Sackler ordered Purdue staff to furnish Quarterly Reports and all other reports provided to the board to the Sackler Families.

1495. In addition, the Sackler Families are beneficial owners of, and exercise complete control over, Rhodes and PF Labs.

1496. Not content with the massive profits generated by their Marketing Efforts for Purdue products, it was recently revealed that the Sackler family also sells unbranded, generic opioids through another corporation that it owns and controls, Rhodes Pharma.

1497. Rhodes Pharma is a Rhode-Island based corporation which produces sells off-patent generic opioids.

1498. Rhodes Pharma is one of the largest such producers of off-patent generic opioids in the United States.

1499. Rhodes Pharma was created in 2007, four months after Purdue pled guilty in a federal suit to criminal charges that it had unlawfully and deceptively marketed OxyContin for over a decade.

1500. Through Rhodes Pharma, the Sackler Family Defendants entered the generic market for OxyContin, and Rhodes Pharma was created by those Defendants for that purpose.

1501. The Sackler Family Defendants beneficially own or control all of the entities owned by the Sackler Families, including PF Labs and Rhodes, and they control them in substantially the same way as they control Purdue and its affiliates, although they may do so using different holding companies and trusts than those used to control Purdue.

1502. The Sackler Families and all Individual Purdue Defendants were the beneficiaries of billions of dollars reaped as a result of the deceptive and unfair Marketing Efforts.

1503. Forbes estimated that the Sackler Families took hundreds of millions of dollars from Purdue in 2015 alone.

1504. Purdue's July 2013 board report stated that the company paid "non-tax distributions" of \$471 million in 2012 and would distribute \$350 million in cash in 2013.

1505. Purdue's July 2010 board report stated that the company paid non-tax distributions of \$389 million in the first half of 2010, and \$381 million in just the first quarter of 2009.

1506. On information and belief, each and every Sackler Family Defendant has received more than \$5 million from Purdue since 2008.

1507. The Sackler Family Board Members were active in their governance of the company along with the other Individual Purdue Defendants and were not silent figureheads.

1508. The Purdue Board of Directors was an informed, active and controlling board.

1509. Each of the Sackler Family Defendants, except David Sackler, have been members of the Board of Purdue Pharma Inc. since the 1990s.

1510. Defendant David Sackler became a board member of Purdue Pharma Inc. in 2012.

1511. Defendant Richard Sackler, son of founder Raymond Sackler, was the inventor and original patent holder of OxyContin, which hit the market in 1996.

1512. Richard Sackler, along with his father Raymond and his uncle Mortimer, played an integral role in the formulation, execution and perpetuation of the Marketing Efforts related to OxyContin.

1513. As testified to by Richard Sackler, the Sackler Family has obtained more than \$1 billion from sales of OxyContin.

1514. Richard Sackler began working for Purdue in the 1970s as Assistant to the President (his father, Raymond), and was promoted to Vice President of Marketing and Sales.

1515. Richard Sackler became Senior Vice President in the early 1990s and ultimately became President in 1999.

1516. In 2003, Richard Sackler resigned from his position as President as concerns over personal liability for the criminal activities of Purdue related to its marketing of opioids arose.

1517. After Richard Sackler resigned from his position as President he continued on as a member of the Board of Directors thereafter to the present, thereby maintaining control over Purdue.

1518. At all times relevant to this complaint, Richard Sackler also served as a trustee of one or more trusts that beneficially own and control Purdue.

1519. Richard Sackler's brother, Defendant Jonathan Sackler, held the position of Vice President of Purdue in 1991, and was promoted to a Senior Vice President in 2000.

1520. Jonathan Sackler also resigned his officer's position in or after 2003, as concerns over personal liability for the criminal activities of Purdue related to its marketing of opioids arose.

1521. Like his brother Richard, Jonathan Sackler continued to serve as a member of the Board of Directors thereafter to the present, thereby maintaining control over Purdue.

1522. At all relevant times, Jonathan Sackler also served as a trustee of one or more trusts that beneficially own and control Purdue.

1523. Defendant Mortimer D.A. Sackler held the position of a Vice President of Purdue at all times relevant to the development, launch, and promotion of OxyContin.

1524. Mortimer Sackler also resigned his officer's position in or after 2003, as concerns over personal liability for the criminal activities of Purdue related to its marketing of opioids arose.

1525. Mortimer Sackler also continued to serve as a member of the Board of Directors thereafter to the present, thereby maintaining control over Purdue.

1526. Mortimer's sister, Defendant Kathe A. Sackler, served as a Vice President of Purdue in 1991, and was promoted to a Senior Vice President by 2000.

1527. Kathe Sackler resigned her officer's position in or after 2003, as concerns over personal liability for the criminal activities of Purdue related to its marketing of opioids arose.

1528. Kathe Sackler also continued to serve as a member of the Board of Directors thereafter to the present, thereby maintaining control over Purdue.

1529. Mortimer and Kathe's sister, Defendant Ilene Sackler Lefcourt, served as Vice President of Purdue at all times relevant to the development, launch, and promotion of OxyContin.

1530. Ilene Sackler Lefcourt resigned her officer's position in or after 2003, as concerns over personal liability for the criminal activities of Purdue related to its marketing of opioids arose.

1531. Ilene Sackler Lefcourt also continued to serve as a member of the Board of Directors thereafter to the present, thereby maintaining control over Purdue.

1532. Defendant Beverly Sackler has been a member of the Board of Directors of Purdue since the 1990s.

1533. At all relevant times, Beverly Sackler also served as a trustee of one or more trusts that beneficially own and control Purdue.

1534. Defendant Theresa Sackler has been a member of the Board of Directors of Purdue since the 1990s.

1535. Defendant David Sackler been a member of the Board of Directors of Purdue since 2012.

1536. Several other individuals who are not Sackler family members served on the Board of Purdue.

1537. Defendant Cecil Pickett became a member of the Board of Purdue in 2010. 1538.

Defendants Paulo Costa and Ralph Snyderman became members of the Board of Purdue in 2012.

1539. Defendant Peter Boer became a member of the Board of Purdue in 2013.

1540. Defendant Judy Lewent was a Board member from at least 2009 to 2014.

1541. Defendants Pickett, Costa, Snyderman, Boer and Lewent were each paid hundreds of thousands of dollars by Purdue for their service.

1542. At all times relevant to this complaint each officer of Purdue including the CEO, Board member, individual Purdue Defendant, and member of the Sackler family had actual knowledge of the unlawful conduct referenced herein.

1543. At all times relevant to this complaint, each officer of Purdue including the CEO, Board member, individual Purdue Defendant, and member of the Sackler family continued to provide substantial.

1544. Each Purdue Board Defendant was paid more than \$500,000 by Purdue for sitting on the Board.

1545. Defendant Snyderman reported to the federal government that Purdue paid him more than \$500,000. Purdue paid him at least \$32,972 for a few months of 2013; \$166,119 in 2014; \$168,887 in 2015; and \$124,360 in 2016.

1546. Defendant Snyderman incurred expenses for travel on 121 days during the time period of 2013 to 2016.

1547. At times relevant to this complaint, the officers of Purdue, including the CEO Individual Purdue Defendants and Defendant Gasdia, reported to the Sackler Family Defendants and the Purdue Board Defendants.

1548. Each Purdue CEO Defendant (John Stewart, Mark Timney, and Craig Landau) has received more than \$1 million from Purdue since 2008.

1549. Defendant John Stewart was Chief Executive Officer of both Purdue companies from June 2007 to January 2014.

1550. Defendant Mark Timney was CEO from January 2014 to June 2017.

1551. Defendant Craig Landau became employed by Purdue in 1999 and has served as CEO since June 2017.

1552. The Individual Purdue Defendants were actively involved in the governance and operation of Purdue, including its Marketing Efforts.

1553. In the course of and as a direct result of their positions with Purdue, each of the Individual Purdue Defendants maintained and exercised control over Purdue and gained and/or possessed actual knowledge of and substantially assisted Purdue's improper illegal Marketing Efforts. They each knowingly aided, abetted, participated in, and benefited from Purdue's illegal and unfair conduct and knowingly aided and abetted each other engaging in such conduct.

1554. Each Individual Purdue Defendant is the direct or indirect beneficiary of profits reaped by Purdue from its sale of opioids.

1555. The Sackler Family Defendants, the Additional Purdue Board Member Defendants, the Purdue CEO Defendants, Rhodes, the Raymond Sackler Trust (through its trustees), and P.F. Labs each knowingly aided, abetted, participated in, substantially assisted and benefitted from the wrongdoing of Purdue as alleged herein.

3. The Individual Purdue Defendants' Knowledge of the Risks Associated with Opioid Use and the Deceptiveness and Falsity of Their Marketing Efforts

1556. OxyContin was created by PF Co. but responsibility for designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and distributing OxyContin and other opioid products was shared among Purdue and Purdue-related companies.

1557. Purdue, including the Individual Purdue Defendants, PF Co., and PF Labs launched and marketed OxyContin in 1996 with one of the biggest pharmaceutical marketing campaigns in history, employing deploying many of the persuasive techniques pioneered by Arthur. They trained and armed a force of approximately 1,000 sales representatives with charts showing OxyContin's purported benefits.

1558. At the launch party for OxyContin, Richard Sacker, then Senior Vice-President responsible for sales stated, “the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white. . . .”

1559. A major thrust of the sales campaign was the unsupportable representation that OxyContin should be prescribed not merely for severe short-term pain associated with surgery or for cancer pain but also for less acute, longer-lasting pain, such as arthritis, back pain, sports injuries, fibromyalgia.

1560. The Sackler Family Defendants viewed any limitations on the sales of opioids as an obstacle to greater profits.

1561. Secret internal correspondence, in the form of an email written by Richard Sackler and sent on June 12, 1997 from Richard Sacker, demonstrates that in 1997 Sackler Family Defendants Richard Sackler and Kathe Sackler, as well as other Purdue executives, determined that doctors were prescribing OxyContin at higher levels and inappropriately due to their wrong belief that OxyContin was weaker than morphine.

1562. Since at least the summer of 1999, the Individual Purdue Defendants, including the Sackler Family Defendants, who were involved in the management of Purdue’s business at that time were aware that prescription opioids would lead to addiction.

1563. Since at least the summer of 1999, they were also increasingly aware that OxyContin could be, and was being, abused.

1564. Since 1999, the Individual Purdue Defendants involved in the management of Purdue were, and have been, aware of the risks and potential of abuse for OxyContin.

1565. In the late summer and early fall of 1999, Purdue secretary Maureen Sara performed an internet research assignment regarding the methods of recreational abuse by drug users of OxyContin in response to a memo written by a Purdue sales representative to the President of Purdue reporting widespread abuse of OxyContin.

1566. The results of Ms. Sara's research were detailed in a memo in October/November 1999, including her finding that users would remove the coating on the OxyContin pills, crush them, cook them, and snort or shoot them (the "Sara Memo").

1567. The Sara Memo, including her finding that users would remove the coating on the OxyContin pills, crush them, cook them, and snort or shoot them was sent to the President of Purdue.

1568. In addition, the Sara Memo was sent directly to the Individual Purdue Defendants who were involved in the management of the company at that time, including Richard Sackler, Jonathan Sackler, and Kathe Sackler.

1569. In a January 26, 2001 email, sales representative Joseph Coggin informed Richard Sackler about a community meeting at a local high school which had been organized by mothers whose children had overdosed on OxyContin and died: "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."

1570. The next month, after learning that a federal prosecutor had reported 59 deaths from OxyContin in one state, Richard Sackler, who knew that report underestimated its numbers, happily reported to Purdue executives, "This is not too bad. It could have been far worse."

1571. In a February 1, 2001 email, Richard Sackler memorialized his solution to the growing problem of overdoses and deaths, blame the victims. He wrote "we have to hammer on

the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.”

1572. In addition, all other Individual Purdue Defendants had knowledge of the deceptiveness, falsity and unlawfulness of the marketing efforts, referenced herein. This was in part as a result of investigations by governmental entities. The investigations by governmental entities resulted in criminal prosecution and guilt.

1573. From 2001 to 2007, Purdue Pharma Inc. and Purdue Pharma L.P. were investigated by 26 states and the U.S. Department of Justice.

1574. In 2007, PF Co. pled guilty to a felony charge for its misleading advertising and promotion of opioids from late 1995 to mid-2001 relating to their risks and potential for abuse and agreed to pay nearly \$700 million in fines and other payments.

1575. At all times relevant to this complaint, PF Co. was a closely held holding company for Purdue Pharma L.P., shared the same headquarters and facilities as Purdue Pharma L.P. and was controlled by the same individuals.

1576. As part of its guilty plea, PF Co. admitted that its supervisors and employees, “with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.”

1577. PF Co. issued a related statement that “[n]early six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A. - approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The

statements also violated written company policies requiring adherence to the prescribing information.”

1578. PF Co. further stated that “we accept responsibility for those past misstatements and regret that they were made.”

1579. In connection with that conduct, Howard Udell, the top lawyer for Purdue Pharma Inc., and the company’s chief medical officer, Paul Goldenheim, after being federally criminally prosecuted for misbranding, admitted that Purdue had marketed OxyContin “with the intent to defraud or mislead” doctors and patients. They were ordered to pay collectively \$34.5 million in fines.

1580. In connection with that same conduct, Michael Friedman, the then-CEO of Purdue Pharma Inc., Purdue Pharma L.P., and PF Co. plead guilty to a criminal misdemeanor.

1581. Michael Friedman retired in June 2007.

1582. Defendant Director Richard Sackler testified that the 2007 felony conviction occurred after an investigation for years prior that involved retraining “everybody” in the company.

1583. The Board of Directors, including those then-sitting Individual Purdue Defendants, voted and approved the plea.

1584. As a result of another suit, Purdue entered into a Consent Judgment in May 2007 with various states related to Purdue’s false and misleading marketing and promotion activities.

1585. Notably, the Consent Judgment ordered that Purdue “shall not make any written or oral claim that is false, misleading, or deceptive” in the promotion or marketing of OxyContin. It also required that those companies provide “fair balance” regarding risks and benefits in all promotion of OxyContin — including about the risk of addiction.

1586. The Consent Judgment further required that Purdue Pharma Inc. and Purdue Pharma L.P. establish, implement, and follow an abuse and diversion detection program that would identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities.

1587. The Consent Judgment required these safeguards to be followed for a 10-year period, from 2007 until 2017.

1588. The Board of Directors, including the sitting members who are the named Individual Purdue Defendants, were informed of, voted for and approved the Consent Judgment.

1589. The sitting directors, including those members who are Individual Purdue Defendants, also voted for and approved the entry into a Corporate Integrity Agreement by Purdue Pharma L.P. with the U.S. government.

1590. The Corporate Integrity Agreement required Purdue to appoint a Compliance Officer who would “be a member of senior management of Purdue,” “make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors,” and “be authorized to report on such matters to the Board of Directors at any time.”

1591. It is also worth noting that Purdue’s directors and CEO were included as “Covered Persons” from 2007 through 2012 under the Corporate Integrity Agreement and that as Covered Persons, they were required to comply with rules prohibiting deception about Purdue’s opioids. They were also required to undergo hours of training to ensure that they fully understood such rules.

1592. Under the Corporate Integrity Agreement, the Purdue directors and CEO were further required to report all violations of the rules prohibiting deception about Purdue’s opioids and were informed that the failure to comply with the rules would have consequences.

1593. Each Purdue director and CEO certified that they had read and understood the rules and that they would comply with them.

1594. According to dozens of previously undisclosed documents, Purdue company officials received reports that the opioid pills were being crushed and snorted; stolen from pharmacies; and that some doctors were being charged with selling prescriptions, and “in the face of this knowledge” Purdue continued to market OxyContin as less prone to abuse and addiction than other prescription opioids.

1595. In a 120-page Justice Department confidential report drafted in 2006 detailing their investigation, federal prosecutors cited emails showing that the Sackler Family was sent reports about the abuse of their opioids.

1596. The report further revealed that Defendant Richard Sackler was told in 1999 while he was president of Purdue Pharma about internet chat room discussions where drug abusers described snorting OxyContin. The report further set forth that other members of the Sackler Family received reports about the abuse of MS Contin.

1597. The report stated that in May 1996, about five months after OxyContin’s approval, Richard Sackler was sent a medical journal article describing how drug abusers were extracting morphine from MS Contin tablets to inject the drug. Richard, Kathe, Jonathan, and Mortimer D.A. Sackler received an email from Purdue Pharma scientist Gary Richtie who researched the issue and informed them of this abuse.

1598. In the following years, Purdue and the Individual Purdue Defendants continued to receive information about the mounting opioid epidemic and regarding the abuse and diversion of opioids and the deceptiveness and success of their Marketing Efforts. In fact, the Individual Purdue Defendants directed and controlled those Marketing Efforts, increasing Purdue’s sales

force by hiring hundreds more reps to visit doctors thousands more times and to push them to prescribe more of the highest doses of opioids. Even Richard Sackler himself went personally into the field on rep visits with doctors to promote opioids.

1599. In July 2007, Purdue employed approximately 300 sales reps. By December 2016, pursuant to the Sackler Family Defendants' orders, that number had increased to approximately 700.

1600. In July 2007, staff told the Sackler Family Defendants that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told those Sacklers that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007 — including several reports in New Hampshire. Staff reported to those Sacklers that they completed only 21 field inquiries in response. Staff also told those Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

1601. That same month, staff reported to the Board that Purdue was exceeding its expected profits, which had a few months prior been estimated at \$407,000,000 but had skyrocketed to more than \$600,000,000. They attributed those profits to "sales effort."

1602. In January 2008, staff reported to the Sackler Family Defendants that Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, and that it conducted only 21 field inquiries in response. Staff also reported to the Sackler Family Defendants that they received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

1603. In July 2008, staff reported to the Sackler Family Defendants that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sackler Family Defendants that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report them to the authorities.

1604. In a corporate compliance quarterly report to the Board 1Q90, dated May 8, 2009, the Board was informed that Purdue had violated its Corporate Integrity Agreement by failing to supervise its sales staff. The Agreement had required Purdue managers to supervise sales reps in person at least 5 days a year because their lobbying doctors poses a high risk of misconduct.

1605. In 2009, an article appeared in the American Journal of Public Health entitled, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy" which described Purdue's marketing devices and use of sales representatives, targeting of high-prescribers, and deception about addiction.

1606. In 2009, the CDC reported that deaths from opioids had recently tripled.

1607. In 2010, an article appeared in *Time* magazine entitled, "The New Drug Crisis: Addiction by Prescription" which described the plight of a Massachusetts patient who had become addicted to OxyContin at age 13.

1608. By the spring 2010, the Individual Purdue Defendants had been told that Purdue could not get product liability insurance to cover OxyContin.

1609. By 2011, governmental entities increasingly identified the growing opioid abuse problem. The White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for "educating healthcare providers about prescription drug abuse ... so they will not over-prescribe[.]"

1610. That same year, the CDC issued a statement revealing that prescription opioid overdoses had reached epidemic levels and identified Purdue's opioids by name.

1611. In 2011, an article appeared in *Fortune* magazine in which Purdue's vice-president Alan Must admitted that the company was "well aware" of criticisms and concerns about its conduct.

1612. In 2012, the Individual Purdue Defendants received specific notice from the U.S. Senate regarding the opioid crisis and Purdue's role and deception of doctors and patients and the Senate's commencement of an investigation regarding the same.

1613. The CEO of Purdue Pharma Inc. and Purdue Pharma L.P. received a letter from the United States Senate warning them of "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers." They were further warned specifically of the danger of patients taking higher doses: "over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks while data suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses." The Senate letter also warned them about Purdue misleading doctors and patients: "There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness."

1614. The Individual Purdue Defendants received notice in that letter that they were under scrutiny, and it demanded that Purdue produce to investigators a set of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."

1615. In a 2013 article in the *Los Angeles Times*, it was revealed that Purdue had been compiling a list for the prior decade of 1,800 doctors suspected of recklessly prescribing its

opioids, but that Purdue had reported only 8% of them to authorities. Purdue attorney Robin Abrams admitted that Purdue had the list but would not agree to disclose it to authorities.

1616. In addition, lawsuits continued to be brought by state authorities against Purdue regarding its unlawful conduct, of which the Individual Purdue Defendants were aware.

1617. For example, in 2014, a lawsuit was pending by the State of Kentucky against Purdue for deceiving doctors and patients about opioids, and in 2015, a lawsuit by the State of New York resulted in an agreement which stated New York's findings that Purdue used misleading materials to promote its opioids and aggressively promoted its opioids to high-prescribing doctors who were later arrested for illegal prescribing.

1618. In 2017, the President of the United States declared the opioid crisis a national public health emergency.

1619. The Individual Purdue Defendants were each aware of all of the foregoing articles, investigations and litigation.

1620. Indeed, the Consent Judgment and Corporate Integrity Statement, which the Purdue Board approved, required Purdue to "continue to review news media stories addressing the abuse or diversion of OxyContin and undertake appropriate measures as reasonable under the circumstances to address abuse and diversion so identified." This in turn provided the Individual Purdue Defendants with numerous warnings that Purdue's drugs caused addiction and death.

1621. The Individual Purdue Defendants knew or should have known about Purdue's deception of doctors and patients.

4. The Individual Purdue Defendants Actively Controlled, Directed and/or Participated in Purdue's Deceptive and Unlawful Marketing Efforts.

1622. The Individual Purdue Defendants controlled and oversaw Purdue's corporate activities and its deceptive Marketing Efforts

1623. The directors and CEO of Purdue Pharma Inc. controlled Purdue Pharma L.P.

1624. The Sackler Family Defendant took pains to ensure the continued flow of money to their family and to maintain the loyalty of Purdue's officers. In an April 18, 2008 email and attached memo sent to Kathe, Ilene, David, Jonathan, and Mortimer Sackler, Richard Sackler recommended John Stewart for CEO, citing his loyalty and stating, "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." He further suggested either selling Purdue in 2008 or milk its profits and "distribute more free cash flow" to themselves. The Board voted to appoint Stewart as President and CEO of Purdue Pharma Inc. and Purdue Pharma LP and pay their family \$250,000,000 in June 2008.

1625. During or about the 1999-2003 time period Purdue attempted to institute a system that would destroy potentially incriminating documents through the self-destruction of company emails at a pre-determined time.

1626. In addition to these unlawful efforts which evidence their consciousness of guilt, board reports exist which establish their actual knowledge of the risks and potential for abuse of Purdue's opioids as well as the Individual Purdue Defendants' control over the Marketing Efforts.

1627. Defendants Richard, Jonathan and Kathe Sackler all were directly aware and supportive of the email destruction project.

1628. Corporate quarterly reports that the Individual Purdue Defendants received establish the fact that they controlled both Purdue Pharma Inc. and Purdue Pharma L.P. A single board controlled both Purdue Pharma Inc. and Purdue Pharma L.P (the "Board").

1629. Quarterly Board reports establish that Purdue did not internally distinguish between Purdue Pharma Inc. and Purdue Pharma L.P. but instead refer to "Purdue". For example, the Board

Reports for the following dates: July 2007, April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, and July 2013 (the “Board Reports”).

1630. The Individual Purdue Defendants controlled and oversaw all facets of Purdue’s Marketing Efforts and closely monitored sales, strategies and content.

1631. In July 2009, Richard Sackler told staff in an email that he was not happy with OxyContin sales and demanded they devise a plan to “boost” them. The next Board meeting in August 2009 was about “all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market.” Richard trumpeted that that \$200,000,000 in profit was at stake. Staff gave detailed reports about sales and their new OxyContin sales campaign with the slogan *Options*.

1632. Another example of the Purdue Board Defendants’ typical conduct and deep involvement in the Marketing Efforts occurred at a November 2009 Board meeting at which Kathe and Richard Sackler asked staff to “identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients;” and give the Sacklers a copy of a report from McKinsey on tactics to increase OxyContin sales. The McKinsey report instructed sales reps to maximize profits by “emphasizing [the] broad range of doses” — which was code for pushing the doses that were highest and most profitable.

1633. Emails between staff members and the Board reveal that the Board asked dozens of questions and orders about the sales campaign in July 2010, even asking if giving free sample

of opioids to doctors would increase sales. They also asked for the details about Purdue's tactics to influence KOLs.

1634. Of note, the Board voted to spend \$226,000,000 on Sales and Promotion in 2010, and to pay the Sackler family \$236,650,000. In April, it voted to pay them another \$141,000,000. As of October 2010, Purdue had paid the Sacklers \$629,000,000 in the first nine months of 2010. In December 2010, the Board voted to pay the family another \$260,000,000.

1635. In 2011, Defendant Richard Sackler's single-minded push for more and more sales continued. After being informed that one week of prescriptions had doubled from Purdue's forecast, Richard emailed the staff: "I had hoped for better results."

1636. Also in June 2011, Richard Sackler demanded to go on face-to-face visits by sales reps with prescribers, despite Defendant Gasdia's concern that such promotion was "a potential compliance risk." To make sure the Sacklers' involvement in marketing stayed secret, staff instructed: "Richard needs to be mum and be anonymous."

1637. Numerous executives, including the CEO, helped to plan Richard Sackler's sales visits, and focused upon their concerns about the potential illegalities involved. One wrote in an email on June 17, 2011: "About 5 last night, John Stewart, the CEO, was walking by my office – I yelled out to stop him – and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with HCPs, or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person."

1638. When Richard Sackler returned from the field, he argued to Defendant Gasdia, Vice President of Sales, that a legally required warning about Purdue's opioids wasn't needed, asserting that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening" ways to describe Purdue opioids.

1639. Other Sackler Family Board members made similar inquiries and directions regarding strategies and Marketing Efforts. For example, in 2011, Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

1640. In January 2012, Jonathan Sackler demanded weekly updates on sales from Defendant Gasdia.

1641. Also in January 2012, Mortimer Sackler focused upon the scheduling of the national sales meeting close to winter break as problematic because doctors might not see a sales rep for a "reminder" for almost two months. Richard Sackler responded by proposing that they cancel the meeting entirely, to the dismay of Purdue's Compliance Officer, Bert Weinstein.

1642. In 2012, Richard Sackler's intense involvement and control over Purdue's staff caused Defendant Gasdia to send an email plea to CEO Defendant Stewart, "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." He bombarded staff with questions and demanded information be provided on sales nearly immediately upon requests.

1643. The Board also discussed in September 2013 sales tactics relative to the DEA's attempts to stop illegal dispensing of opioids at CVS and Walgreens and how Purdue could get

around the new safeguards by shifting to mail-order pharmacies, specialty pharmacies, or Purdue distributing opioids to patients directly.

1644. An end of year assessment of tactics presented in October 2013, informed the Board that a relationship marketing program targeting Boston had increased opioid prescriptions by 959%.

1645. In early 2014, Jonathan Sackler voiced his concern over his potential liability, studying collections of news reports and asking staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers. In December 2015, he requested briefing on the effects of public health efforts to address opioid addiction on sales of Purdue's OxyContin.

1646. Defendant Kathe Sackler's activities in 2014 included being involved in a secret plan for Purdue to reap profits by expanding into the business of selling drugs to treat the very epidemic they created – Project Tango. She participated in a confidential call in September 2014 discussing it.

1647. In internal documents regarding the Project, she and staff admitted that opioids and addiction are “naturally linked” and that the tactic of blaming victims for their addiction as untrustworthy patients was a lie. She and staff determined that Purdue should expand across “the pain and addiction spectrum,” to become “an end-to-end pain provider.” Purdue illustrated the end-to-end business model with a picture of a dark hole labeled “Pain treatment” that a patient could fall into — and “Opioid addiction treatment” waiting at the bottom. The plan was presented to the Board in February 2015. The Project was discontinued one month later in March 2015.

1648. Of note, the Sacklers began in June 2016 to discuss a new version of Project Tango, focusing this time on selling and profiting from the overdose antidote NARCAN.

1649. In addition to the other instances described herein, Defendant Theresa Sackler's activities include an email inquiry on May 6, 2017 to staff asking what they were doing to fight back to convince doctors and patients to keep using OxyContin.

1650. Also worth noting is the fact that the Board Reports establish that the directors and CEO, including the Individual Purdue Defendants, oversaw Purdue's sales representatives and were fully aware of and endorsed their activities.

1651. The sales force for Purdue's opioids was more than half the headcount of the company.

1652. The Board Reports clearly establish that the Individual Purdue Defendants tracked the exact number of sales representatives; the exact number of visits they made to doctors to urge them to prescribe Purdue products; which drugs they promoted; how many visits they averaged per workday; how much each visit cost Purdue; and the company's plan for sales visits in each upcoming quarter.

1653. The Individual Purdue Defendants were instrumental in the hiring and management of sales representatives and their activities. They approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales "territories" in which representatives would target doctors.

1654. In February 2008, the Sackler Family Defendants ordered Purdue to "begin expanding the sales force by an additional 100 sales representatives beginning effective as of April 1, 2008," as indicated in the February 8, 2008 board minutes. They had been informed that adding 100 sales reps would enable Purdue to make 12,000 more sales visits each month.

1655. Pressure by Defendants Jonathan, Kathe and Mortimer Sackler on staff to keep opioid sales levels high appears in a March 11, 2008 email by Kathe Sackler demanding that staff

identify pressures that would make those levels challenging and provide “quantification of their negative impact on projected sales.”

1656. Throughout the relevant time period, the Purdue Board Defendants continued to vote to increase sales staff and to reward them with bonuses for selling so many opioids. For example, in March 2009, the Board voted to give sales reps and managers bonuses of 103 percent of Purdue’s target and to increase the base pay of sales staff for 2009.

1657. In April 2009, the Sackler Family Defendants had a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales reps the company should employ, and how many prescribers each rep would visit each year.

1658. The Individual Purdue Defendants’ mandate to increase sales visits is evident in Richard Sackler’s response in April 2012 to a mandatory weekly report which stated that sales reps achieved 9,021 prescriptions in a week. He pushed Defendant Gasdia for a commitment that reps would get weekly prescriptions to 10,000.

1659. In 2014, Purdue continued its practice of paying bonuses to sales reps based upon increasing doctors’ prescriptions, even though other companies had rejected such practices.

1660. In February 2014, Purdue identified Defendant Fathalla Mashali as a “high value” doctor and ordered reps to keep promoting drugs to him even after reps warned Purdue that he was involved in diversion and abuse.

1661. In February 2014, with increasing concern over liability, Purdue abolished the detailed Quarterly Reports which provided a paper trail establishing the Individual Purdue Defendants’ knowledge of sales visits and marketing.

1662. By 2017, the Board approved a 2018 target for sales rep visits to prescribers of 1,050,000 visits – almost double the number of sales visits they had ordered years ago in 2010.

1663. The Individual Purdue Defendants oversaw the tactics that sales representatives used to push opioids.

1664. The Board Reports demonstrate the oversight by the Individual Purdue Defendants of the marketing claims that representatives pitched to doctors during sales visits.

1665. The October 2010 Board Report establishes that they were presented with a “review of call notes” recorded by Purdue sales representatives which “suggested potential comparative claims of superiority of Purdue products relative to competitors,” and deceptive promotion of opioids as treatment for “minor pain,” and hundreds of examples of deceptive marketing that required “extensive remedial actions.”

1666. The January 2011 Board Report establishes that Purdue analyzed its initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor to “16.7 minutes in front of the customer.”

1667. The August 2011 Board Report establishes that the Individual Purdue Defendants actually monitored sales representatives’ emails to doctors to ensure that Purdue’s policy of no written communications, which was to conceal their wrongful conduct, was followed. Moreover, that emails that had been sent in violation of that policy were investigated and then discussed at board meetings.

1668. The Individual Purdue Defendants also oversaw and ultimately controlled the marketing and promotional strategies engaged in by sales representatives and Purdue.

1669. One such strategy was paying high-prescriber physicians to promote Purdue opioids.

1670. To track the effectiveness and profitability of their unscrupulous strategy, the Board reviewed a list of the exact number of conferences and dinner meetings, with attendance figures,

and received data on the prescribing trends of the attendees. Further tracking effectiveness and profitability, the Board received information on the amounts paid to certain doctors (for example, that a doctor was paid \$29,000 in the first half of 2012), and detailed reports on the Return On Investment that Purdue gained from paying doctors to promote its drugs.

1671. There is no doubt that the Board was fully aware of the dangers in paying doctors to promote opioids. For example, this fact is established in the August 2011 and November 2011 Board Reports stating that it was “a high-risk activity, in view of the potential for off-label or other improper promotional conduct by third parties during such activities.”

1672. After Congress required disclosure of drug company payments to doctors, the Board was told in April 2010 that there were “significant compliance implications” for Purdue.

1673. Another unlawful marketing and promotion strategy that the Individual Purdue Defendants had actual knowledge of, oversaw and controlled was the pushing of patients to higher doses of opioids.

1674. For example, in March 2008, Richard Sackler directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. In response, Richard responded by calling an employee at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. He ultimately prepared his own graphs and had the Board reject the presented sales plan.

1675. In February 2008, Richard Sackler directed Purdue management to “measure our performance by Rx’s by strength, giving higher measures to higher strengths” and copied Jonathan and Mortimer Sackler on the instruction.

1676. In April 2010, staff told the Board that they were pushing back against the “threat” of public health rules that were aimed at limiting high doses of opioids and that Purdue would oppose precautions that would influence doctors to consult with specialists before prescribing the highest doses of opioids.

1677. Despiciously, the Defendants went so far as to characterize a proposal by public health authorities to require doctors to consult with pain specialists before prescribing opioid doses higher than 80mg/day as a “threat”. This is established in multiple board reports including April 2010, July 2010, October 2010, November 2011).

1678. Board Reports throughout 2011 establish the Individual Purdue Defendants were focused on volume and profits and not a market volume decided by patient needs. In fact Board Reports establish Purdue defined volume loss as a of the failure to achieve target levels of the sales of high dose products. Moreover, the Board minutes establish that in the fall of 2011 they lamented that Purdue had lost more than \$800 million in revenue because patients weren’t taking enough 40 mg and 80 mg doses.

1679. In November 2012, the Board received the results of a confidential study of 57,000 patients that Purdue performed explicitly to determine how opioid dose “influences patient length of therapy.” They showed that patients on the highest doses “are the most persistent.” The “Recommended Actions” presented to the Board included “additional workshops for the sales force” and “specific direction” to the sales representatives about using higher doses to keep patients on drugs longer. Staff told the Board that encouraging higher doses “is a focal point of our promotion,” and that sales reps would “emphasize the importance” of increasing patients’ opioid doses, as soon as 3 days after starting treatment.

1680. Marketing Efforts overseen and directed by the Individual Purdue Defendants had a positive impact and an email sent in May 2013 prior to the June 2013 Board meeting stated that Purdue's executives were pleased to report that "initiatives to validate increased total daily doses are having impact in the field."

1681. The Board received reports in July 2013 regarding the training of Purdue sales reps to use newly developed marketing materials to get patients on higher doses of opioids for longer periods of time.

1682. In May 2014, David, Jonathan and Richard Sackler received a confidential memo from Richard and Jonathan's father – Raymond Sackler – regarding Purdue's strategy that specially included putting patients on high doses of opioids for longer periods of time.

1683. In turn, the pushing of higher doses of opioids fed into Purdue's and the Individual Defendants' strategy to keep patients on opioids for a longer period of time, which also increases patients' risk of addiction and death..

1684. The November 2012 Board Report provided the Board received with the confidential results of a Purdue study of 57,000 patients performed explicitly to determine how opioid dose "influences patient length of therapy." The results revealed that patients on the highest doses "are the most persistent."

1685. As a result of those findings, the Individual Purdue Defendants were explicitly advised of Purdue's unlawful marketing strategy. Specifically, that encouraging higher doses "is a focal point of our promotion," and that sales representatives would "emphasize the importance" of increasing patients' opioid doses, as soon as 3 days after starting treatment. The November 2012 Board Report also recommended "additional workshops for the sales force" and "specific direction" to the sales representatives about using higher doses to keep patients on drugs longer.

1686. The July 2013 Board Report establishes that the Board reviewed specific sales materials including but not limited to “two new patient profiles designed to improve patient identification and titration” – to get more opioid-naïve and elderly patients on higher doses of opioids for longer periods of time. Moreover, that the Board was told of the exact research behind the sales strategy. Specifically, that higher doses would keep patients on drugs longer because Purdue had found that “83% of patients who discontinued were never titrated to higher doses.”

1687. The Individual Purdue Defendants had actual knowledge, oversaw, provided substantial assistance and controlled another facet of Purdue’s unlawful strategy and Marketing Efforts’, specifically the targeting prescribers who did not have special training in opioids (primary care doctors, nurse practitioners, and physician assistants) because they “show the highest responsiveness” to Purdue’s sales push.

1688. The Individual Purdue Defendants had actual knowledge, oversaw, provided substantial assistance and controlled another facet of Purdue’s unlawful strategy and Marketing Efforts, specifically, to target elderly patients. The July 2013 Board Report establishes that Purdue’s promotion was “targeted to HCPs that practice in the long-term care setting,” and describes the use of advertising that “leverages images of older patients.”

1689. The Individual Purdue Defendants had actual knowledge, oversaw, provided substantial assistance and controlled another facet of Purdue’s unlawful strategy and Marketing Efforts. Specifically, Purdue’s strategy of using “savings cards” to lure patients into using its opioids for longer periods of time was overseen and controlled by the Individual Purdue Defendants. Board Reports informed the Board of the thousands of cards that were used each quarter, of how the company calculated the Return On Investment, and that the explicit goal of the savings card program was to hook patients to “remain on therapy longer.”

1690. Staff also gave regular reports at Board meetings on usage of cards. For example, in August 2009, they reported that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported the summer before.

1691. In June 2012, the Board was informed of the expansion of the use of savings cards because Purdue's data showing they led to 60% more patients remaining on OxyContin longer than 90 days.

1692. In January 2013, the Board was informed of a sensitivity analysis on the savings card performed by Purdue to maximize their impact. The result was Purdue's increase of its dollar value and extension of the program period to 15 months, along with the creation of promotional materials, such as videos, to support those tactics.

1693. The Individual Purdue Defendants were informed of legal and policy developments, including New Hampshire law regarding savings cards. They also tracked New Hampshire legislation to regulate dinners where doctors are paid to promote drugs, and were made aware of "specific concerns" about New Hampshire legislation that would have imposed tighter regulation on opioids.

1694. The Individual Purdue Defendants had actual knowledge, oversaw, provided substantial assistance and controlled another facet of Purdue's unlawful strategy and Marketing Efforts, specifically, Purdue's efforts to steer patients away from using safer alternatives. A May 2013 email for a June 2013 Board meeting discussed Purdue's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity."

1695. Indeed, in February 2008, the Individual Purdue Defendant purposefully chose not to research whether crush-proof opioids were really safer for patients before pushing them on and

selling them to millions of patients. They carefully avoided making a paper trail on their discussions of the issue.

1696. The Individual Purdue Defendants had actual knowledge, oversaw, provided substantial assistance and controlled another facet of Purdue's unlawful strategy and Marketing Efforts, specifically, Purdue's deceptive and misleading websites.

1697. The Individual Purdue Defendants also were informed of reports, which even reached 5000 in a single quarter in or about July 2007, of adverse results due to the use of Purdue's opioids and oversaw and controlled Purdue's response.

1698. Upon information and belief, each of the foregoing reports was sent to every Individual Purdue Defendant on the Board at the time of such reports. Specifically, Defendants Richard Sackler, Jonathan Sackler, Beverly Sackler, Theresa Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler Lefcourt, and John Stewart were sent all of the reports discussed above, in July 2007, April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, and July 2013.

1699. Defendants Cecil Pickett, Peter Boer, and Judy Lewent were sent the board reports in April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, November 2012, and July 2013.

1700. Defendants David Sackler, Paulo Costa, and Ralph Snyderman were sent the board reports in November 2012 and July 2013.

1701. Defendant Craig Landau was sent the board reports in July 2007, April 2010, July 2010, October 2010, January 2011, August 2011, November 2011, and November 2012.

1702. The Additional Purdue Board Member Defendants voted with the Sackler Family Defendants on every single one of the hundreds of votes that came before them during their respective tenures on the Board.

1703. Defendants Boer, Lewent, Pickett, Costa, and Snyderman each collected hundreds of thousands of dollars from Purdue, including thousands of dollars from opioid sales in New Hampshire. In exchange for the money, Boer, Lewent, Pickett, Costa, and Snyderman did what the Sacklers wanted every step of the way. They each knowingly, intentionally, and repeatedly directed Purdue's unfair and deceptive sales and marketing campaign in New Hampshire, to the great cost of patients and families.

1704. Each of the CEO Individual Defendants had actual knowledge, oversaw, provided substantial assistance and controlled Purdue's unlawful sales and marketing activities as referenced throughout.

1705. When CEO Individual Defendant John Stewart became CEO in 2007, he had already spent 33 years with Purdue Pharma Canada, as its President since 1990.

1706. Stewart oversaw and controlled Purdue's strategy to drive patients to higher doses and longer periods on Purdue drugs to keep the total kilograms of opioids within Purdue forecasts. Stewart also oversaw and controlled the sales tactics designed to help doctors overcome concerns that increasing length and dose would cause more patient to get addicted and die.

1707. While at Purdue, Stewart participated in the Marketing Efforts aimed at encouraging prescribers to prescribe opioids more aggressively and deceptively dispel their safety and addiction concerns.

1708. For example, in a March 7, 2008 email, Stewart presented the details of the OxyContin savings card program to the Board, explaining that offering savings cards increased the share of patients who use branded OxyContin by fifteen percent.

1709. In December 2009, Stewart prepared 2010 objectives for the sales and marketing team, including how many times sales reps should visit prescribers to promote opioids and how managers should supervise the reps. Stewart wrote that the target for face-to-face promotion to prescribers would be 540,000 sales visits, and staff would have to report the number of sales visits, compared to the target and compared to the prior year, at the end of every quarter.

1710. In September 2013, Stewart initiated Project Turbocharge aimed at drastically increasing OxyContin sales calls and changing the way Purdue targeted prescribers. His initiative was renamed E2E: Evolve to Excellence and was the theme of the 2014 National Sales Meeting.

1711. Defendant Mark Timney became CEO in January 2014, a time when public health experts were trying to save patients' lives by warning against high doses of opioids.

1712. Timney received regular internal reports on the media coverage of opioid-related issues, including the devastating effects of their Marketing Efforts.

1713. Timney directed Marketing Efforts through email communications with staff, such as a February 26, 2014 email directing that Purdue "target KOLs who would respond" to the launch of a competitor opioid with data showing why Purdue's opioids should be used instead in certain patients. In another email in August 2014, he sent the entire company a 100-day strategy update containing his vision for growth.

1714. Timney approved Purdue's unlawful "strategic initiative" to fight back and "maintain 2013 dose mix" in 2014. Also during Timney's tenure as CEO, Purdue settled the investigation of its opioid business with the state of New York and provided testimony in the

investigation by the Commonwealth of Kentucky that Purdue deceived doctors and patients about its opioids.

1715. Defendant Craig Landau worked for years as a Purdue executive, including stints as Executive Medical Director and Chief Medical Officer, prior to becoming CEO in 2017. Since then, Purdue made thousands of sales visits to promote opioids in New Hampshire, and many New Hampshire patients who had been prescribed Purdue opioids overdosed and died.

1716. In a May 2, 2017 email Landau sent to the Sacklers, he included his plan for Purdue to become an even more dominant opioid seller. As CEO he consistently defended the Sacklers, even writing to the President of Tufts University on November 13, 2017 to rebut, falsely, negative news coverage.

1717. As a long-time Purdue employee from 1985 until he retired at the end of 2014, Russell Gasdia was integrally involved in every part of Purdue's deceptive Marketing Efforts as Vice President of Sales and Marketing. For example, he was integral in developing the fundamentals of getting more patients on opioids at higher doses for longer periods; the targeting of prolific opioid prescribers; paying doctors to promote Purdue opioids; concealing Purdue's list of problem doctors codenamed Region Zero; and deciding what would get a sales rep hired or fired.

1718. Gasdia carried out hundreds of orders from Richard Sackler and others and was integral in promoting Purdue opioids in New Hampshire by in part ensuring sales reps visited New Hampshire prescribers thousands of times. He was responsible for overseeing Purdue's regional sales managers and sales reps, Purdue's training and marketing departments, and its forecasting, sales administration and contracting, all with full knowledge of the deceptiveness of the Marketing Efforts.

1719. Each of the Individual Purdue Defendants controlled and directed that sales representatives made thousands of visits to doctors in New Hampshire to implement the deceptive Marketing Efforts.

1720. Defendant Board member Richard Sackler testified that the sales representatives were the main way that Purdue promoted its opioids. Richard Sackler also testified that the key to getting doctors to prescribe and keep prescribing Purdue opioids was regular visits from the sales force.

1721. Each of the Individual Purdue Defendants controlled and directed payments to New Hampshire doctors to promote Purdue's drugs.

1722. Defendants Richard Sackler, Jonathan Sackler, Beverly Sackler, Theresa Sackler, Mortimer Sackler, Kathe Sackler, and Ilene Sackler Lefcourt (directors in 2007) directed Purdue to enter into the Consent Judgment.

1723. Defendants Richard Sackler, Jonathan Sackler, Beverly Sackler, Theresa Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler Lefcourt, David Sackler, Cecil Pickett, Paulo Costa, Ralph Snyderman, Peter Boer, Judy Lewent, John Stewart, Mark Timney, and Craig Landau also directed Purdue to violate the Consent Judgment.

1724. The Individual Purdue Defendants actually knew and should have known that Purdue's sales strategies were deceptive and increased the risk of addiction, overdose, and death.

1725. The Individual Purdue Defendants also had actual knowledge of, controlled and oversaw research results which were at odds with Purdue's marketing and promotional claims.

1726. The Individual Purdue Defendants similarly had actual knowledge of, controlled and oversaw Purdue's improper response to indications that certain doctors were over prescribing its opioids. For example, in the July 2007 Board Report establishes that the Individual Purdue

Defendants were informed of the 572 “Reports Of Concern” that Purdue sales representatives submitted to the company about doctors they visited to promote opioids and the mere 21 “field inquiries” Purdue had decided to conduct in response to those reports.

1727. Having addicted their victims to opioids, the Sackler Family sought to profit by manufacturing and selling a purported cure for the addiction they fueled.

1728. Through Rhodes Pharma, the Sackler Family recently obtained a patent for a drug it touts helps to wean addicts from opioids.

1729. Purdue has recently expanded its overseas sales.

1730. From the 2007 convictions until 2018, the Sackler Family Defendants voted dozens of times to pay out Purdue’s opioid profits to their family — in total more than four billion dollars.

1731. The Sackler Family Defendants knew that substantial amounts of that sum came from opioid sales in New Hampshire.

H. The Distributor Defendants’ Unlawful Failure To Prevent Diversion And Monitor, Report, And Prevent Suspicious Orders

1732. The Distributor Defendants are opioid distributors in Coos County.

1733. The Distributor Defendants purchased opioids from manufacturers, such as the named Defendants herein, and sold them to pharmacies throughout Coos County.

1734. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Coos County.

1735. According to the Drug Enforcement Administration Automation of Reports and Consolidated Orders System (“ARCOS”), from 2006 to 2016, pharmaceutical distributors, including Distributor Defendants, supplied a drastically increasing and alarming number of opioid pain medications to Coos County area.

1. The Distributor Defendants Have a Duty to Prevent Diversion.

1736. Under federal law, opioids are categorized as "Schedule II" drugs because they have a "high potential for abuse" and the potential to cause "severe psychic or physical dependence" and/or "severe psychological ... dependence." 21 U.S.C. § 812(b)(2)(A, C).

1737. Each Defendant Distributor was required to register. As a "registrant," each Defendant Distributor was a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed by statute.

1738. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and state law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from the County as well as those orders that the Distributor Defendants knew or should have known were likely to be diverted into the County.

1739. Distributor Defendants, as distributors of opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

1740. Distributor Defendants, as wholesale drug distributors, are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

1741. New Hampshire state law also imposes the above duties upon the Distributor Defendants.

1742. Under the laws of the State of New Hampshire, all distributors and manufacturers of controlled substances must be licensed and registered with the State. *See, e.g.*, N.H. R.S.A. 318:51-a.

1743. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

1744. Each Distributor Defendant has an affirmative duty under federal and state law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§ 823(b)(1). Those requirements are adopted and incorporated into state law.

1745. Each Distributor Defendants breached its duties and engaged in systemic and knowing patterns of failure under those laws.

1746. The Distributor Defendants were each on notice that the controlled substances they manufactured and distributed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy and problematic purposes.

1747. The Distributor Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers within Coos County during this time period.

1748. On December 27, 2007, the U.S. Department of Justice, Drug Enforcement Administration, sent a letter to Defendant Cardinal stating, “This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b).”

1749. The DEA has provided briefings to each of the Defendant Distributors and conducted a variety of conferences regarding their duties.

1750. The DEA sent a letter to each of the Defendant Distributors on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate.²⁰² The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”

1751. The DEA has found that if “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

1752. As the DEA advised the Defendant Distributors in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

²⁰² See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enft Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription dmg abuse problem om nation currently faces. "), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”²⁰³

1753. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.²⁰⁴

1754. In the September 27, 2006 letter the DEA sent to each Distributor Defendant, it warned that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”²⁰⁵ The letter also instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”²⁰⁶ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”²⁰⁷

1755. The DEA sent a second letter to each of the Defendant Distributors on December 27, 2007 (the “DEA Letter”).²⁰⁸ This Letter reminded Defendant Distributors of their statutory

²⁰³ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter “Rannazzisi Letter”] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

²⁰⁴ See Brief for HDMA and NACDS, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

²⁰⁵ Rannazzisi Letter at 2.

²⁰⁶ *Id.* at 1.

²⁰⁷ *Id.* at 2.

²⁰⁸ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Dmg. Enft Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1: 12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” *See* 21 CFR 1301.74(b).

1756. Giving specific guidance on their regulatory duties in connection with identifying and reporting suspicious orders, the DEA Letter further states:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a registrant need not wait for a “normal pattern” to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant’s customer base and the pattern throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating “excessive purchases” do not comply with the requirement to report suspicious orders, even if the registrant calls such reports “suspicious order reports.”

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.

1757. These requirements are intended to insure that distributors of controlled substances such as opioids are operating a “closed system” to guard against diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

1758. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role and responsibilities.²⁰⁹

1759. The Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the New Hampshire State Board of Pharmacy.

²⁰⁹ Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf’t Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter “Brief for HDMA and NACDS”]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation’s primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, <https://www.healthcaredistribution.org/about> (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, <https://www.nacds.org/about/mission/> (last visited Aug. 21, 2017).

1760. Distributor Defendants were aware of these obligations yet failed to comply with them.

1761. The Distributor Defendants are also members of the Healthcare Distribution Management Association (“HDMA”).

1762. The HDMA created “Industry Compliance Guidelines” which stressed the critical role of each member of the supply chain in distributing controlled substances.

1763. The HDMA guidelines provided that “[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

1764. The HDMA guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor 's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.²¹⁰

2. The Distributor Defendants Failed in Their Duties and Allowed Diversion.

1765. The Distributor Defendants failed to comply with their legal duties under federal and state law to maintain effective controls against diversion of prescription opiates and design and operate a system to disclose suspicious orders of controlled substances.

1766. The Distributor Defendants similarly failed to monitor, detect, investigate, refuse to fill suspicious orders of prescription opiates.

²¹⁰ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

1767. The Distributor Defendants failed in their duties to design and operate a system to disclose to the registrant suspicious orders of prescription opiates and to inform authorities of suspicious orders.

1768. The Distributor Defendants violated state and federal rules, codes, and regulations for distributors by failing to properly report suspicious orders.

1769. The Distributor Defendants knew or should have known that they were supplying vast amounts of dangerous drugs to Coos County that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

1770. The Distributor Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs from at least 2007 through the present time.

1771. The Distributor Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the flow of these drugs in Coos County.

1772. The Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

1773. The Distributor Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

1774. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Coos County.

1775. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

1776. The sheer volume of the increase in opioid pain medications being distributed to retailers, should have put the Distributor Defendants on notice to investigate and report such orders.

1777. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Coos County and the surrounding area.

1778. Upon information and belief, the Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy within Coos County and the surrounding area from 2007 to the present.

1779. The Distributor Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Coos County and the surrounding area.

1780. The Distributor Defendants also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Coos County and the surrounding area.

1781. The Distributor Defendants made substantial profits from the opioids sold in Coos County and the surrounding area.

1782. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the residents of Coos County and the surrounding area.

1783. By the actions and inactions described above, the Distributor Defendants caused great harm to Coos County.

3. Multiple Enforcement Actions against the Distributor Defendants Confirm their Compliance Failures.

1784. In 2008, Defendant McKesson paid a \$13.2 million fine to settle claims regarding suspicious orders from internet pharmacies.²¹¹

1785. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

1786. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."²¹²

1787. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record \$150 million fine and suspend the sale of controlled substances from distribution centers in several states.²¹³

1788. In 2008, Defendant Cardinal paid a \$34 million penalty to resolve allegations that it failed to report suspicious opioid orders.²¹⁴

1789. Despite this past penalty, in 2017, it was announced that Defendant Cardinal agreed to a \$44 million fine to "resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York."²¹⁵

²¹¹ <http://www.wvgazettemail.com/news-health/20161218/suspicious-drug-order-rules-never-enforced-by-state>. (last visited May 30, 2017).

²¹² <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders> (last visited May 30, 2017).

²¹³ *Id.*

²¹⁴ <https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0> (last visited May 30, 2017).

²¹⁵ https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.7049c4431465 (last visited on May 17, 2017).

1790. Defendant AmeriSource faced a criminal inquiry “into its oversight of painkiller sales” in 2012.²¹⁶ They have paid out fines for similar claims to the state of West Virginia.

1791. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Coos County.

1792. The DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. The Drug Enforcement Administration’s Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions (the “Registrant Actions”):

On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (Orlando Facility) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (Auburn Facility) for failure to maintain effective controls against diversion of hydrocodone;

On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (Lakeland Facility) for failure to maintain effective controls against diversion of hydrocodone;

²¹⁶ <http://www.nytimes.com/2013/06/12/business/walgreen-to-pay-80-million-settlement-over-painkiller-sales.html> (last visited on May 17, 2017).

On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (Swedesboro Facility) for failure to maintain effective controls against diversion of hydrocodone;

On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Strafford, Texas Distribution Center (Strafford Facility) for failure to maintain effective controls against diversion of hydrocodone;

On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (2008 MOA) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility, and Strafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Maryland (McDonough Facility), Valencia, California (Valencia Facility) and Denver, Colorado (Denver Facility);

On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center (Lakeland Facility) for failure to maintain effective controls against diversion of oxycodone;

On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA

1793. Rather than abide by public safety statutes, Defendant Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to

“halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.²¹⁷

I. Manufacturer Defendants’ Unlawful Failure to Prevent Diversion and Monitor, Report, and Prevent Suspicious Orders.

1794. Manufacturer Defendants were subject to the same federal and state laws as the Distributor Defendants relating to monitoring, reporting and prevention with respect to prescription opiates.

1. The Manufacturer Defendants Have a Duty to Prevent Diversion.

1795. Each Manufacturer Defendant was required to register with the DEA. As a “registrant,” each Manufacturer Defendant was a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed by statute.

1796. The Manufacturer Defendants owe a duty to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from the County as well as those orders that the Distributor Defendants knew or should have known were likely to be diverted into the County.

²¹⁷ See Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.d84d374ef062; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b44410552cde.

1797. The Manufacturer Defendants, as distributors of opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

1798. Under the laws of the State of New Hampshire, all distributors and manufacturers of controlled substances must be licensed and registered with the State. *See, e.g.*, N.H. R.S.A. 318:51-a.

1799. The Manufacturer Defendants had access to and possessed the information that was necessary to monitor, report, and prevent suspicious orders and to prevent diversion through the "chargeback" practice engaged in with opioid distributors.

1800. Through this practice, a manufacturer gains access to information, like the product sold, identity of a purchaser (such as a pharmacy) and the volume sold, from a distributor after the distributor sells the manufacturer's product at a price below a specified rate and requests a "chargeback" from the manufacturer.

1801. In this manner, the Manufacturer Defendants had knowledge of the volume, frequency, and pattern of opioid orders being placed and filled.

1802. The Manufacturer Defendants also possessed information regarding distribution and prescribing levels obtained through their sales representatives and from databases of health care providers regarding prescribing levels which they maintain.

2. The Manufacturer Defendants Failed in Their Duties and Allowed Diversion.

1803. The Manufacturer Defendants failed to comply with their legal duties under federal and state law to maintain effective controls against diversion of prescription opiates and design and operate a system to disclose suspicious orders of controlled substances.

1804. The Manufacturer Defendants similarly failed to monitor, detect, investigate, refuse to fill suspicious orders of prescription opiates.

1805. The Manufacturer Defendants failed in their duties to design and operate a system to disclose to the registrant suspicious orders of prescription opiates and to inform authorities of suspicious orders.

J. The Retail Pharmacies Knew of and Contributed to the Illegal Diversion of Prescription Opioids

1806. Defendants CVS, Walgreens, Walmart, and Rite-Aid are both large-scale distributors of opioids and pharmacies across the country that distribute opioids directly to patients.

1807. Defendant Retail Pharmacies chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

1808. Each of the Defendant Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

1809. Defendant Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in New Hampshire. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to New Hampshire and Coos County.

1810. Defendant Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

1811. Defendant Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, the Retail Pharmacies had direct knowledge

of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Coos County in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, Defendant Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but they failed to do so.

1. The Retail Pharmacies Have a Duty to Prevent Diversion

1812. Defendant Retail Pharmacies, as participants in the supply chain of opioid distribution, are responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

1813. Defendant Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

1814. As registrants under the CSA, Defendant Retail Pharmacies possessed the duty to prevent diversion.

1815. Under the laws of the State of New Hampshire, all distributors of controlled substances, including Defendant Retail Pharmacies, must be registered with the State. *See, e.g.*, NH Rev Stat ch. 318; NH Ph. ch. 300.M.G.L. c. 94C, § 7.

1816. The New Hampshire Attorney General, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

1817. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

1818. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

1819. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

1820. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by Defendant Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

1821. According to industry standards, if a pharmacy finds evidence of prescription diversion, the New Hampshire Board of Pharmacy must be contacted, among others.

1822. Despite their legal obligations as registrants under New Hampshire law, Defendant Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.

1823. Performance metrics and prescription quotas adopted by Defendant Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations.

1824. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of Defendant Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

1825. Upon information and belief, this problem was compounded by Defendant Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

1826. Upon information and belief, Defendant Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of

prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

1827. Upon information and belief, Defendant Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

1828. Upon information and belief, Defendant Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

1829. Upon information and belief, Defendant Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

1830. Defendant Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

1831. Defendant Retail Pharmacies similarly did not take any steps or actions to cease the flow of opioids into communities, including Coos County, and instead continued to participate in the activities causing the oversupply and to profit from it.

2. The Retail Pharmacies Failed in Their Duties and Allowed Diversion.

1832. Defendant Retail Pharmacies failed to comply with their legal duties under federal and state law to maintain effective controls against diversion of prescription opiates and design and operate a system to disclose suspicious orders of controlled substances.

1833. Defendant Retail Pharmacies similarly failed to monitor, detect, investigate, refuse to fill suspicious orders of prescription opiates.

1834. Defendant Retail Pharmacies failed in their duties to design and operate a system to disclose to the registrant suspicious orders of prescription opiates and to inform authorities of suspicious orders.

3. Multiple Enforcement Actions against the Retail Pharmacies Confirms their Compliance Failures.

1835. Defendant Retail Pharmacies have long been on notice of their failure to abide by state law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, New Hampshire policies and practices of the Retail Pharmacies.

i. CVS

1836. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

1837. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the United States Department of Justice (“DOJ”). It nonetheless treated these fines as the cost of doing business and has allowed

its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the law.

1838. As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

1839. This fine was preceded by numerous others throughout the country.

1840. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the law and filling prescriptions with no legitimate medical purpose.

1841. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the law.

1842. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

1843. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the law by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

1844. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the law by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions

with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

1845. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, “based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”

1846. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

1847. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

1848. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the law by filling prescriptions signed by prescribers with invalid DEA registration numbers.

ii. Walgreens

1849. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens

operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

1850. Walgreens also has been penalized for serious and flagrant violations of the law. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the law, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

1851. The settlement resolved investigations into and allegations of violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

1852. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

1853. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens' attitude that profit outweighed compliance with the law or the health of communities.

1854. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

1855. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and New Hampshire (\$200,000).

1856. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.²¹⁸

1857. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.

iii. Rite Aid

²¹⁸ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), available at <https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state>.

1858. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

1859. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the law.

1860. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the law that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated.

iv. Walmart

1861. On information and belief, other Retail Pharmacy Defendants, including Walmart have engaged in similar conduct in violation of their responsibilities to prevent diversion.

1862. The Retail Pharmacy Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids.

1863. Numerous state drug diversion prosecutions have occurred in which prescription opioid pills were procured from Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

1864. The litany of state actions against the Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the law and other laws and regulations that govern the distribution and dispensing of prescription opioids.

1865. Throughout the country and in New Hampshire in particular, the Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

1866. On information and belief, from the seat of their retail pharmacy operations, the Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Coos County and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state regulatory actions, including prosecutions of pill mills in the area.

1867. On information and belief, the Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

1868. On information and belief, because of (among others sources of information) regulatory and other actions taken against the Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

1869. The Retail Pharmacies’ actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

1870. Each Defendant turned a blind eye to suspicious orders of opioids and their actions and omission in failing to prevent diversion effectively and failing to monitor, report, and prevent

suspicious orders have contributed significantly to the increased volume of opioids sold and resulted in exorbitant addiction, overdose and death and black markets for the diverted opioids.

EQUITABLE ESTOPPEL AND FRAUDULENT CONCEALMENT

1871. Plaintiff's claims are further subject to equitable estoppel and tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from Plaintiff and Plaintiff's community. Plaintiff did not know or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

1872. As set forth herein, the Manufacturer Defendants utilized the services and efforts of various Front Groups and KOL to conceal their role in shaping, editing, and approving misleading and fraudulent content in the Marketing Efforts, including in prescribing guidelines, scientific literature and promotional materials, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. The Manufacturer Defendants secretly controlled messaging, influenced prescribing practices and drove sales of opioids.

1873. The Manufacturer Defendants not only concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic, they further falsely attributed it instead solely to abuse and inappropriate prescribing.

1874. Through their public statements, omissions, marketing, and advertising, the Manufacturer Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

1875. Each Defendant also affirmatively acted to conceal their wrongful conduct by misrepresenting their cooperation with law enforcement as well as their compliance with their duty to monitor and report suspicious orders of opioids.

1876. Defendants acted to purposefully conceal their unlawful conduct from Plaintiff and to fraudulently assure the public, the County and the County's communities that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status and to continue generating profits. Defendants affirmatively and fraudulently assured the public, the County and Plaintiff's communities that they were and are working with law enforcement and others to prevent diversion to curb the opioid crisis. Defendants further made broad promises to change their ways insisting they were good corporate citizens. Their repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

1877. Further, Defendants have also concealed and prevented discovery of information regarding their transactions, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities and identify the potential defendants in this litigation. The United States District Court for the Northern District of Ohio ordered on April 11, 2018, that Defendants produce the transactional ARCOS data, and held that because the transaction data had not yet been produced, the Plaintiffs could not identify potential defendants, stating

This means Plaintiff[s] still do[] not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff[s] still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS

spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiff[s'] claims, but also to the Court's understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

1878. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

1879. In light of their statements to the media, in legal filings, and settlements, Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes and lack of cooperation with law enforcement set forth herein.

1880. Through their public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or presumptive knowledge of facts sufficient to put it on notice of potential claims.

1881. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

LEGAL CAUSES OF ACTION

FIRST CAUSE OF ACTION

**VIOLATION OF NEW HAMPSHIRE REGULATION OF BUSINESS PRACTICES FOR
CONSUMER PROTECTION RSA 358-A - DECEPTIVE ACTS AND PRACTICES
(AGAINST ALL DEFENDANTS)**

1882. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

1883. Based on the aforementioned, Defendants have violated New Hampshire Regulation of Business Practices for Consumer Protection RSA 358-A in using deceptive practices in the conduct of trade and/or commerce within the State of New Hampshire.

1884. Plaintiff brings this action pursuant to RSA 358-A:10 “Private Actions” of this statute.

1885. Plaintiff is entitled to treble damages pursuant to RSA 348-A:10 as Defendants’ conduct was a willful and knowing violation of New Hampshire Business Practices for Consumer Protection.

1886. Plaintiff and its residents have been injured by reason of Defendants’ violation of RSA 358-A.

**SECOND CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)**

1887. Plaintiff incorporates the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

1888. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Coos County by their production, promotion, and marketing of opioids for use by residents of Coos County.

1889. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

1890. Defendants' conduct constitutes a public nuisance.

1891. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

1892. Plaintiff and its residents suffered special injuries distinguishable from those suffered by the general public.

THIRD CAUSE OF ACTION
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, et seq.
(AGAINST MANUFACTURER DEFENDANTS)

1893. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

1894. Plaintiff brings this Count against the Manufacturer Defendants, including the Individual Purdue Defendants (collectively, the "RICO Marketing Defendants").

1895. The RICO Marketing Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

1896. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's

affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C. § 1962(c).

1897. Defendants’ illegal scheme was hatched by an association-in-fact enterprise among and between the Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO Marketing Enterprise, whose purposes were to expand the market for opioids to treat chronic pain and to engage in the unlawful sales of opioids. The RICO Marketing Defendants’ scheme allowed them to make billions in unlawful sales of opioids. As a direct result of the RICO Marketing Defendants’ fraudulent scheme and Marketing Efforts, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiff experienced injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Marketing Defendants’ misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

A. THE RELEVANT ENTERPRISES

1898. The term “enterprise” is defined as including “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). The definition of “enterprise” in Section 1961(4) includes legitimate and illegitimate enterprises.

1899. The RICO Defendants engaged in two relevant illegal association-in-fact enterprises, which are pled in the alternative: the Opioid Marketing Enterprise and the Opioid Diversion Enterprise, which is detailed in Count Three below.

1900. The Opioid Marketing Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of (1) the Manufacturer Defendants, including their employees and agents; (2) Front Groups, including their employees and agents; and (3) KOLs; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Marketing Enterprise. This Enterprise's purposes were to create and expand a new market for opioids for chronic pain treatment, further their illegal Marketing Efforts, increase their profits and revenues, and minimize losses and sell as many as opioids as possible, thereby creating the opioid epidemic, including, but not limited to, the black markets for diverted opioids.

1901. To accomplish its purposes, the Opioid Marketing Enterprise engaged in the Marketing Efforts and systematically and continuously misrepresented to the general public, doctors, and the County the risks of using opioids for chronic pain treatment, and flouted the requirements to investigate and prevent the ensuring waive of suspicious orders.

1902. All entities are distinct persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Defendants to fraudulently market opioids as scientifically proven as safe and effective. The Opioid Marketing Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioid Marketing Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for the common purpose of ensuring the prescription of opioids for chronic pain.

1903. At all relevant times, the RICO Marketing Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by implementing the unfair, illegal and deceptive Marketing Efforts. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

1904. Each of the Manufacturing Defendants relentlessly promoted opioids as having little to no risk of addiction, as being safe and effective for the treatment of long-term chronic pain and/or other uses for which the drugs were not approved. The Manufacturing Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturing Defendants through and in collaboration with the Front Groups – a formidable partnership that marketed to hundreds of thousands of prescribers across the country, including prescribers in Coos County. The relationship was strengthened, in part, by the KOLs and other doctors, including physicians that held different leadership roles at different times across the various entities participating in the enterprise over the years.

1905. At all relevant times, the RICO Marketing Enterprise (a) had an existence separate and distinct from each RICO Marketing Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Marketing Defendants; (d) characterized by interpersonal relationships among the RICO Marketing Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

1906. Each member of the RICO Marketing Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Marketing Enterprise's disregard for the Manufacturer Defendants' duties to exercise due care through their misrepresentation of the nature of the drugs through the Marketing Efforts and aggressive promotion of them for chronic pain for which they knew the drugs were not safe or suitable.

1907. The RICO Marketing Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

1908. Within the RICO Marketing Enterprise, there were interpersonal relationships and common communication through which the Marketing RICO Defendants shared information on a regular basis.

1909. These interpersonal relationships also formed the organization of the RICO Marketing Enterprise. The RICO Marketing Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

1910. Each of the RICO Marketing Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Marketing Defendants participated in the operation and management of the RICO Marketing Enterprise by directing its affairs, as described herein.

1911. While the RICO Marketing Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

1912. The RICO Marketing Defendants exerted substantial control over the RICO Marketing Enterprise by their membership in the PCF and through their contractual relationships.

1913. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

1914. The Center for Public Integrity and The Associated Press obtained “internal documents shedding new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.

1915. Not surprisingly, the RICO Marketing Defendants are members of and/or participant in the PCF. In 2012, membership and participating organizations included Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (i.e., Allergan), and Teva (the parent company of Cephalon). Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise.

1916. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the RICO Marketing Defendants’ interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were “encouraged to attend in person” at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a “Guest Speaker.”

1917. The 2012 Pain Care Forum Meeting Schedule demonstrates that the RICO Marketing Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape

the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

1918. Taken together, the interaction and length of the relationships between and among the RICO Marketing Defendants reflects a deep level of interaction and cooperation between groups in a tightly knit industry. The RICO Marketing Defendants were not separate entities operating in isolation or entities forced to work together in a closed system. The RICO Marketing Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful marketing and sale of prescription opioids.

1919. As described above, the RICO Marketing Defendants began working together as early as 2006 through the PCF and/or the HDA to promote the common purpose of their enterprise.

1920. Plaintiff is informed and believes that the RICO Marketing Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE RICO ENTERPRISE

1921. From approximately the late 1990s to the present, each Manufacturing Defendant exerted control over the RICO Marketing Enterprise and participated in the operation or management of the affairs of the RICO Marketing Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature, electronic and print advertising, sales and promotional materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- c. Selecting, cultivating, promoting and paying KOLs and Front Groups based solely on their willingness to communicate and distribute the Manufacturer Defendants' messages about the use of opioids for chronic pain;
- d. Providing substantial opportunities for KOLs and Front Groups to participate in research studies on topics the Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature; and
- e. Paying KOLs to serve as consultants or on the Manufacturer Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs.

1922. The KOLs and the Front Groups participated in the operation or management of the affairs of the RICO Marketing Enterprise, directly or indirectly, by making and disseminating representations regarding opioids drugs that were consistent with the Manufacturer Defendants' messages and concealing their connections to such Defendants.

1923. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described herein.

1924. The scheme devised and implemented by the RICO Diversion Defendants amounted to a common course of conduct.

C. PATTERN OF RACKETEERING ACTIVITY.

1925. The RICO Marketing Defendants conducted and participated in the conduct of the RICO Marketing Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Marketing Defendants Engaged in Mail and Wire Fraud.

1926. The RICO Marketing Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the RICO Marketing Enterprise through a pattern of racketeering activities within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

1927. The RICO Marketing Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Marketing Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Marketing Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

1928. The RICO Marketing Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain.

1929. In devising and executing the illegal scheme, the RICO Marketing Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of

materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Marketing Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

1930. The RICO Marketing Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Marketing Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

1931. The RICO Marketing Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturer Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;
- d. Written representations and telephone calls between the Manufacturer Defendants and Front Groups regarding or relating to the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

- e. Written representations and telephone calls between the Manufacturer Defendants and KOLs regarding or relating to the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally
- f. APF's Treatment Options beginning in 2007 and continuing afterward;
- g. APF's Policymaker's Guide beginning in 2011 and continuing thereafter;
- h. Endo's pamphlet Understanding You Pain, available on Endo's website;
- i. The Board Reports; and
- j. Responsible Opioid Prescribing, beginning in 2007 and continuing thereafter via wires.

1932. On information and belief, the RICO Marketing Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

1933. Each Manufacturer Defendant manufactured and shipped their prescription opioids to the Distributor Defendants in this jurisdiction.

1934. The RICO Marketing Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities.

1935. Plaintiff is informed and believes that the RICO Marketing Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

1936. The RICO Marketing Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

1937. The mail and wire transmissions described herein were made in furtherance of the RICO Marketing Defendants' scheme and common course of conduct to deceive and misrepresent the safety of their opioids

1938. The RICO Marketing Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Marketing Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Marketing Defendants.

1939. The RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

1940. The RICO Marketing Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

1941. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding marketing prescription opioids.

1942. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had

the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

1943. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Marketing Defendants while Plaintiff was left with substantial injury through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the RICO Marketing Enterprise and in furtherance of its fraudulent scheme.

1944. The pattern of racketeering activity alleged herein and the RICO Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the enterprise.

1945. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

1946. Many of the precise dates of the RICO Marketing Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the RICO Enterprise depended upon secrecy.

1947. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and Plaintiff. The RICO Marketing Defendants calculated and intentionally crafted the RICO Marketing Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or Plaintiff.

1948. By engaging in the Marketing Efforts, the RICO Marketing Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

1949. It was foreseeable to Defendants that engaging in the Marketing Efforts would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

1950. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

1951. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic.

1952. Plaintiffs' injuries, as described above in allegations expressly incorporated herein by reference as alleged throughout this complaint, include:

- a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- b. Costs associated with providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;
- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- i. Costs associated with increased burden on Plaintiff's judicial systems, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' communities;
- l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

1953. Plaintiff's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for the RICO Marketing Defendants' conduct, Plaintiff would not have incurred the expenditures required as a result of the plague of drug-addicted residents.

1954. Plaintiff's injuries and those of her citizens were directly caused by the RICO Marketing Defendants' racketeering activities.

1955. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

1956. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

FOURTH CAUSE OF ACTION
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, et seq.
(AGAINST MANUFACTURER AND DISTRIBUTOR DEFENDANTS)

1957. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

1958. Plaintiff brings this Count against the Manufacturer and Distributor Defendants (collectively, the "RICO Diversion Defendants").

1959. The RICO Diversion Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Diversion Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

1960. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c).

1961. For over a decade, the RICO Diversion Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO

Diversion Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers.

1962. As “registrants,” the RICO Diversion Defendants operated and continue to operate within the “closed-system” created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the “CSA”). The CSA restricts the RICO Diversion Defendants’ ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

1963. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of controlled substances.

1964. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the RICO Diversion Enterprise (as defined below) systematically and fraudulently misrepresented the risks of using opioids for chronic pain and violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the RICO Diversion Defendants’ scheme, members of the RICO Diversion Enterprise repeatedly engaged in unlawful misrepresentations and sales of painkillers which, in turn, artificially and illegally increased the

annual production quotas for opioids allowed by the DEA. In doing so, the RICO Diversion Defendants allowed hundreds of millions of pills to enter the market which allowed them to generate obscene profits.

1965. Defendants' illegal scheme was hatched by an association-in-fact enterprise among and between the Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Diversion Defendants were associated with, and conducted or participated in, the affairs of the RICO Diversion Enterprise, whose purposes were to expand the market for opioids to treat chronic pain and to engage in the unlawful sales of opioids and to deceive the public and federal and state regulators into believing that the RICO Diversion Defendants were faithfully fulfilling their statutory obligations. The RICO Diversion Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Diversion Defendants' fraudulent scheme and Marketing Efforts, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiff experienced injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

A. THE RELEVANT ENTERPRISES

1966. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises.

1967. The Opioid Diversion Enterprise is an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that these Defendants were faithfully fulfilling their statutory obligations and increase the quota for and profit from the increased volume of opioid sales in the United States, thereby creating the opioid epidemic. The RICO Defendants' scheme allowed them to further their purpose to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiff suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic.

1968. Members of the Opioid Diversion Enterprise, finding it impossible to legally achieve their ever-increasing sales ambitions, systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

1969. Each of these entities, including the RICO Diversion Defendants, is a “person” distinct from the RICO Enterprise.

1970. Alternatively, the RICO Diversion Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the “HDA”) is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an “enterprise” within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

1971. On information and belief, each of the RICO Diversion Defendants is a member, participant, and/or sponsor of the HDA and/or utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to this Count.

1972. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the RICO Diversion Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Diversion Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

1973. In addition, the Opioid Marketing Enterprise and the Opioid Diversion Enterprise operated as and constituted a single enterprise, which is also pled in the alternative as the RICO Enterprise, and all of the allegations applicable to such separate enterprises are alleged as to that single enterprise. The Distributor Defendants were willing participants in, and beneficiaries of, the Marketing Defendants’ campaign of deception. They profited from the Marketing Efforts’

newly expanded market for chronic pain treatment and furthered the RICO Enterprise's goal of profiting from that market by violating legal requirements to report suspicious orders. All RICO Diversion Defendants were thereby able to profit from both the legal and illegal drug markets created by the RICO Enterprise's success in establishing the long-term opioid treatment market and the ensuing addiction epidemic. The Distributor Defendants were aware of the fraudulent and deceptive Marketing Efforts engineered by the Manufacturing Defendants, Front Groups and KOLs, but sought only to profit from it.

1974. At all relevant times, the RICO Diversion Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Diversion Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

1975. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

1976. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970 (the "CSA"). The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. As reflected in

comments from United States Senators during deliberation on the CSA, the “[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.” Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.

1977. All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction like the opioid epidemic that has occurred.

1978. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders. The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to “know their customers.”

1979. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.” When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant's production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies. '

1980. At all relevant times, the RICO Diversion Enterprise (a) had an existence separate and distinct from each RICO Diversion Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Diversion Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Diversion Defendants; (d) characterized by interpersonal relationships among the RICO Diversion Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Diversion Enterprise's disregard for the RICO Diversion Defendants' duties to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

1981. The RICO Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Diversion Defendants liable for disregarding their duty to prevent diversion.

1982. Members of the Pain Care Forum and the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believes that the PCF and its members, and the HDA, poured millions into lobbying efforts.

1983. The RICO Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Diversion Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating state and federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption, and was as well as the resultant opioid epidemic. The increased volume of opioids prescribed resulted in exorbitant addiction, overdose and death and black markets for the diverted opioids prescribed.

1984. The RICO Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines,

such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

1985. Within the RICO Diversion Enterprise, there were interpersonal relationships and common communication through which those Defendants shared information on a regular basis.

1986. These interpersonal relationships also formed the organization of the RICO Diversion Enterprise. The RICO Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

1987. Each of the RICO Diversion Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Diversion Defendants participated in the operation and management of the RICO Diversion Enterprise by directing its affairs, as described herein.

1988. While the RICO Diversion Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

1989. The RICO Diversion Defendants exerted substantial control over the RICO Diversion Enterprise by their membership in the PCF, the HDA, and through their contractual relationships.

1990. First, the certain RICO Diversion Defendants are members of and/or participant in the PCF. In 2012, membership and participating organizations included the HDA, Endo, Purdue,

Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (i.e., Allergan), and Teva (the parent company of Cephalon). Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA. Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

1991. Second, the HDA was a means to the formation of interpersonal relationships and an organization between the RICO Diversion Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint were members. The HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between manufacturers and distributors at high executive levels.

1992. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.” The HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

1993. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Diversion Defendants. The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year-end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

1994. After becoming members, the distributors and manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: “This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”
- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributors and manufacturer members.
- c. Health, Beauty and Wellness Committee: “This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain.” Participation in this committee includes distributors and manufacturer members.
- d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.
- e. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing,

FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.

- f. Bar Code Task Force: Participation includes distributor, manufacturer and service provider members.
- g. eCommerce Task Force: Participation includes distributor, manufacturer and service provider members.
- h. ASN Working Group: Participation includes distributor, manufacturer and service provider members.
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes distributor and manufacturer members.

1995. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the RICO Diversion Enterprise’s organization.

1996. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.” The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.” The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. The Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

1997. A third means by which the RICO Diversion Defendants maintained their interpersonal relationships was by working together and exchanging information and driving the

unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

1998. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the *Washington Post*, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.

1999. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

2000. The contractual relationships among the RICO Diversion Defendants also include vault security programs. The RICO Diversion Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Diversion Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

2001. Taken together, the interaction and length of the relationships between and among the RICO Diversion Defendants reflects a deep level of interaction and cooperation between groups in a tightly knit industry. The RICO Diversion Defendants were not separate entities operating in isolation or entities forced to work together in a closed system. The RICO Diversion Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful distribution and sale of prescription opioids.

2002. According to articles published by the Center for Public Integrity and The Associated Press, the PCF -- whose members include the Manufacturers and the Distributors' trade association -- has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade." From 2006 to 2016 the Distributors and Manufacturers worked together through the PCF to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA has continued its work, without interruption, since at least 2000, if not longer.

2003. As described above, the RICO Diversion Defendants began working together as early as 2006 through the PCF and/or the HDA to promote the common purpose of their enterprise.

2004. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE RICO ENTERPRISE

2005. From approximately the late 1990s to the present, each RICO Diversion Defendant exerted control over the RICO Diversion Enterprise and participated in the operation or management of the affairs of the RICO Diversion Enterprise, directly or indirectly, in the following ways:

- a. Violating the CSA and causing massive diversion of opioids by failing to investigate suspicious orders;

- b. Violating the CSA and causing massive diversion of opioids by failing to maintain adequate controls against diversion of prescription opioids;
- c. Refusing to identify, investigate or report suspicious orders of prescription opioids being diverted into the illicit drug market; and
- d. Disseminating false and misleading statements to the public claiming that they were complying with their legal obligations.

2006. During the time period alleged in this Complaint, the RICO Diversion Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their federal and state obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as detailed herein:

2007. The RICO Diversion Defendants paid nearly \$800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the PCF. The RICO Diversion Defendants were members of their PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

2008. The RICO Diversion Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

2009. The RICO Diversion Defendants applied political and other pressure on the Department of Justice and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

2010. The RICO Diversion Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

2011. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Diversion Defendants.

2012. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids. On information and belief, the "know your customer" questionnaires informed the RICO Diversion Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

2013. The RICO Diversion Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Diversion Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in

178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.

2014. The RICO Diversion Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify suspicious orders and report them to the DEA.

2015. The RICO Diversion Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

2016. The RICO Diversion Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Diversion Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Diversion Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

2017. The scheme devised and implemented by the RICO Diversion Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY.

2018. The RICO Diversion Defendants conducted and participated in the conduct of the RICO Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(1)(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(1)(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States. _

1. The RICO Diversion Defendants Engaged in Mail and Wire Fraud.

2019. The RICO Diversion Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the RICO Diversion Enterprise through a pattern of racketeering activities within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

2020. The RICO Diversion Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Diversion Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the RICO Diversion Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Diversion Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

2021. The RICO Diversion Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

2022. In devising and executing the illegal scheme, the RICO Diversion Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Diversion Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

2023. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

2024. The RICO Diversion Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the RICO Diversion

Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Diversion Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Defendants' DEA registrations;
- c. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- e. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- f. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- g. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- h. Documents for processing and receiving payment for prescription opioids;
- i. Payments from the Distributor Defendants to the Manufacturer Defendants;
- j. Rebates and chargebacks from the Manufacturer Defendants to the Distributor Defendants;
- k. Payments to Defendants' lobbyists through the PCF;
- l. Payments to KOLs and the Front Groups;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

2025. On information and belief, the RICO Diversion Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or

received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

2026. Each Manufacturer Defendant manufactured and shipped their prescription opioids to the Distributor Defendants in this jurisdiction.

2027. The RICO Diversion Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Diversion Defendants made misrepresentations about their compliance with federal and state laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

2028. At the same time, the RICO Diversion Defendants misrepresented the superior safety features of their order monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

2029. Plaintiff is also informed and believes that the RICO Diversion Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

2030. The RICO Diversion Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

2031. The mail and wire transmissions described herein were made in furtherance of the RICO Diversion Defendants' scheme and common course of conduct to deceive regulators and the public that the RICO Diversion Defendants were complying with their state and federal obligations

to identify and report suspicious orders of prescription opioids all while the RICO Diversion Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Diversion Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

2032. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

2033. The RICO Diversion Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Diversion Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

2034. The RICO Diversion Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

2035. The RICO Diversion Defendants hid from the general public, and suppressed and/or ignored warnings from third-parties, whistleblowers and governmental entities, about the

reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

2036. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

2037. Indeed, for the RICO Diversion Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding refusing to report suspicious orders.

2038. As described herein, the RICO Diversion Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

2039. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Diversion Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Diversion Defendants through their participation in the RICO Diversion Enterprise and in furtherance of its fraudulent scheme.

2040. The pattern of racketeering activity alleged herein and the RICO Diversion Enterprise are separate and distinct from each other. Likewise, the RICO Diversion Defendants are distinct from the enterprise.

2041. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

2042. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and Plaintiff. The RICO Diversion Defendants calculated and intentionally crafted the RICO Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third-parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The RICO Diversion Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

2043. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

2044. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

2045. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

**D. THE RICO DEFENDANTS MANUFACTURED, SOLD AND/OR
DEALT IN CONTROLLED SUBSTANCES AND THEIR
CRIMES ARE PUNISHABLE AS FELONIES.**

2046. The RICO Diversion Defendants conducted and participated in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

2047. The RICO Diversion Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

2048. Each of the RICO Diversion Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

2049. Pursuant to the CSA and the Code of Federal Regulations, the RICO Diversion Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

2050. The RICO Diversion Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Diversion Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

2051. For example, the DEA and Department of Justice began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and Department of Justice wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.

2052. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the *Los Angeles Times* reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The *LA Times* uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring." Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several

years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”

2053. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt’s response was that everyone knew what was going on in Florida but they had no duty to report it.

2054. The foregoing examples reflect the RICO Diversion Defendants’ pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants, including the Registrant Actions.

2055. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

2056. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

2057. Many of the precise dates of the RICO Diversion Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the RICO Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

2058. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

2059. It was foreseeable to the RICO Diversion Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

2060. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

E. DAMAGES

2061. The RICO Diversion Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic.

2062. Plaintiffs' injuries, as described above in allegations expressly incorporated herein by reference as alleged throughout this complaint, include:

- a. Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;
- b. Costs associated with providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

- c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;
- d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;
- e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;
- f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;
- g. Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy;
- h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;
- i. Costs associated with increased burden on Plaintiff's judicial systems, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;
- j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;
- k. Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiffs' communities;
- l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and
- m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

2063. Plaintiff's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for the RICO Diversion Defendants' conduct, Plaintiff would not have paid the expenditures required as a result of the plague of drug-addicted residents.

2064. Plaintiff's injuries and those of her citizens were directly caused by the RICO Diversion Defendants' racketeering activities.

2065. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

2066. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

FIFTH CAUSE OF ACTION
RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1962(d), et seq.
(AGAINST ALL RICO DEFENDANTS)

2067. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

2068. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with their respective RICO Marketing and/or Diversion Enterprises (the "RICO Enterprises") and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the relevant RICO Enterprises through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d), it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

2069. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the relevant RICO Enterprises through a pattern of racketeering activity, as incorporated by reference below.

A. THE RICO ENTERPRISE.

2070. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning each of the RICO Enterprises.

B. CONDUCT OF THE RICO ENTERPRISE.

2071. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the Conduct of each of the RICO Enterprises.

C. PATTERN OF RACKETEERING ACTIVITY.

2072. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the “Pattern of Racketeering Activity.”

D. DAMAGES.

2073. The RICO Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

2074. Plaintiff’s injuries were proximately caused by the RICO Defendants’ racketeering activities. But for the RICO Defendants’ conduct, Plaintiff would not have paid the expenditures required as a result of the plague of drug-addicted residents.

2075. Plaintiff’s injuries were directly caused by the RICO Defendants’ racketeering activities.

2076. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

2077. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

SIXTH CAUSE OF ACTION
FRAUD
(AGAINST ALL DEFENDANTS)

2078. Plaintiff incorporates the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

2079. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

2080. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

2081. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

2082. Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions.

2083. Defendants' intentionally did not alter or correct the disseminated information they knew to be fraudulent.

2084. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff and its residents suffered actual pecuniary damage.

2085. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

SEVENTH CAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

2086. Plaintiff incorporates the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

2087. Plaintiff conferred a benefit upon Defendants by making payments, directly or indirectly, for opioids that were sold or used in Coos County, which payments Defendants accepted without protest or defect and retained, profited and benefitted from them.

2088. Plaintiffs further conferred a benefit upon Defendants by paying for Defendants' cost of the harms caused by Defendants' improper distribution activities.

2089. Defendants' activities permitted opioids to be diverted which resulted in the unlawful expansion of the opioid market, including the black market for Defendants' drugs, and the supply of massive amounts of opioids into the County and New Hampshire.,

2090. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefitted from Plaintiff and its residents.

2091. Defendants' retention of those benefits would be inequitable based on the circumstances set forth herein, including their false and deceptive marketing and promotion campaign and their omissions of and failure to state material facts in connection with their marketing of opioids as well as their failure to report suspicious orders and prevent diversion. Defendants have thus been unjustly enriched by their actions which contributed to Coos County's opioid epidemic.

2092. Plaintiff and its residents expected that Defendants had provided all the necessary and accurate information regarding the risks and had not misrepresented any material facts regarding those risks.

2093. Defendants have been unjustly enriched at the expense of Plaintiff.

EIGHTH CAUSE OF ACTION
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

2094. Plaintiff incorporates the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

2095. Defendants have a duty to exercise reasonable care in the manufacturing, advertising, marketing, selling and/or distributing of opioids.

2096. Defendants have a duty to not expose Plaintiff to an unreasonable risk of harm.

2097. Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

2098. The Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids.

2099. The Manufacturer Defendants breached their duties to exercise due care by misrepresenting the nature of the drugs through the Marketing Efforts and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable, upon which Plaintiff and its residents reasonably relied.

2100. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations and omission alleged and incorporated herein upon which Plaintiff and its residents reasonably and foreseeably relied.

2101. As entities involved in the manufacture, distribution and/or marketing of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under New Hampshire law.

2102. Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies.

2103. Defendants knew or should have known that they were supplying vast amounts of dangerous drugs in the County that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

2104. Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the manufacture and flow of these drugs to Plaintiff.

2105. Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

2106. Defendants, in the interest of their own massive profits, intentionally failed in this duty.

2107. Defendants breached their duties to exercise due care in the business of distribution of dangerous opioids by failing to monitor for, failing to report, and filling highly suspicious orders. Because the very purpose of these duties was to prevent the resulting harm – misuse and/or diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

2108. Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff, in addition to other misrepresentations alleged and incorporated herein.

2109. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity to prevent and/or ameliorate such distinctive and significant dangers.

2110. Defendants were negligent in disclosing to relevant authorities, including the County, suspicious orders for opioids.

2111. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

2112. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution, and sale of their prescription opioids.

2113. Defendants were negligent by marketing, distributing, and selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to Plaintiffs.

2114. The method by which Defendants created this market was by marketing, distributing, and selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

2115. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

2116. Defendants are in a class of a limited number of parties that can legally manufacture and/or distribute opioids, which places them in a position of great trust by the County.

2117. The trust placed in Defendants by Plaintiff through the license to manufacture, sell and/or distribute opioids in the County creates a duty on behalf of Defendants to prevent diversion of the medications it supplies to illegal purposes.

2118. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the County and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

2119. Defendants were and continue to be required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

2120. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

2121. Defendants are in exclusive control of the management of the opioids they distributed to pharmacies and drug stores in the County.

2122. Coos County is without fault and the injuries to the County and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.

2123. As a proximate result of the foregoing, Defendants and their agents have caused Coos County to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, and the County has borne the massive costs of these illnesses and conditions by having to provide necessary medical care, facilities, and services for treatment of County residents. These costs also include, but are not limited to, increased law enforcement and judiciary usage, educational and community programs, drug support programs, drug take back programs, addiction programs, the provision of Naloxone to its law enforcement, emergency medical providers, and schools, the provision of care and services to the families and children of those suffering from opioid-related disability or incapacitation, and diminished tax revenue and business investment, all at the County's expense.

NINTH CAUSE OF ACTION
CONSPIRACY
(AGAINST ALL DEFENDANTS)

2124. Plaintiff incorporates the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

2125. Defendants engaged in a civil conspiracy in connection with their unlawful marketing, sale, distribution and/or diversion of opioids into Coos County.

2126. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their conspiratorial enterprise.

2127. The Manufacturer Defendants further unlawfully marketed and promoted opioids nationwide and in Coos County in furtherance of that conspiracy.

2128. Such Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote and expand the use of opioids for the management of pain to mislead physicians, patients, and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

2129. This wrongful, deceptive, unfair or unlawful network is interconnected and interrelated and relied upon such Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Manufacturer Defendants, and such Defendants relied upon the materials to intentionally mislead medical providers and consumers and of the appropriate uses, risks and safety of opioids.

2130. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Manufacturer Defendants committed overt acts in furtherance of their conspiracy.

2131. All Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in connection with their unlawful distribution and diversion of opioids into Coos County.

2132. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids in Coos County and each agreed to disregard their drug reporting obligations.

2133. Defendants acted tortuously in agreement with each other in pursuit of a common object to expand the opioid market.

2134. Defendants acted with agreement and a common object to commit unlawful acts and/or lawful acts unlawfully, as alleged herein, and acted purposely, with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse, to create the injuries alleged herein.

2135. Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and encouragement in that conduct.

2136. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing and/or have occurred within the last year.

2137. Defendants' conspiracy, and actions and omissions in furtherance thereof, proximately caused and/or substantially contributed to the direct and foreseeable losses and damages alleged herein.

TENTH CAUSE OF ACTION
AIDING AND ABETTING
(AGAINST ALL DEFENDANTS)

2138. Plaintiff incorporates the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

2139. Each Defendant had actual knowledge of the unfair, deceptive and unlawful acts, practices and omissions of the other Defendants but continued to knowingly provide substantial assistance or encouragement to the other Defendants in committing the acts and omissions supporting each causes of action alleged herein and did so with unlawful intent and knowledge that such parties were perpetuating an illegal marketing and promotion scheme to wrongfully increase sales of opioids beyond legitimate medical purposes and were failing to comply with mandated reporting requirements yet continuing to substantially assist each other in their wrongful actions.

2140. Each Defendant rendered substantial assistance despite their knowledge that the marketing, promotional and distribution-related activities were unlawful, unfair, deceptive and fraudulent.

2141. By each Defendant's actions alleged above, each said Defendant aided and abetted the commission of the causes of action alleged herein.

2142. As a direct and proximate result of Defendants' unlawful marketing and promotion scheme and failure to comply with mandated reporting requirements and all the activities performed in connection therewith, to which Defendants provided substantial assistance, Plaintiff sustained damages and losses and demands to be made whole.

ELEVENTH CAUSE OF ACTION
ENHANCED COMPENSATORY DAMAGES

2143. Plaintiff re-alleges all paragraphs of this Complaint as if set forth fully herein.

2144. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions.

2145. For all the aforementioned reasons, Defendants are liable for enhanced compensatory damages as they engaged in wanton, malicious and oppressive conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, as to the FIRST, SECOND, THIRD, FOURTH, FIFTH, SIXTH, SEVENTH, EIGHTH, NINTH TENTH and ELEVENTH Causes of Action, awarding Plaintiff:

- i. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- ii. double or treble damages, attorneys' fees and costs pursuant to New Hampshire Regulation of Business Practices for Consumer Protection Law RSA 358-A;
- iii. double or awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;
- iv. enhanced compensatory damages;
- v. interest;
- vi. an order enjoining Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them, from engaging in unlawful sales of prescription opioid pills and ordering temporary, preliminary or permanent injunction; and
- vi. such other and further relief as this Court deems just and proper.

REQUEST FOR A JURY TRIAL

Plaintiff hereby demands a jury trial.

Dated: October 18, 2019
 Concord, New Hampshire

/s/Robert J. Bonsignore
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